

Veterinary treatments and other substances used in finfish aquaculture in Ireland.

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Summary

Over recent years the finfish aquaculture sector has contracted in Ireland. The bulk of this sector is accounted for by marine salmon production. A number of substances are used in finfish farming that may give rise to discharges to the aquatic environment.

Substances discharged from finfish aquaculture locations

The main medicinal treatments used in finfish aquaculture by volume (active ingredient) are antibiotics, especially oxytetracycline, although the pattern of medicinal use in finfish aquaculture changes frequently. The sea lice treatments currently used are Slice (active ingredient emamectin benzoate), Excis (cypermethrin) and Ektobann (teflubenzuron) and Alphamax (deltamethrin). While the greatest overall quantity of sea lice treatment product used from 2004-2006 was Slice, there is a relatively low proportion of active ingredient. Overall use of sea lice treatments as volume active ingredient during the 2004-2006 period were:

Teflubenzuron > Emamectin > Cypermethrin > Deltamethrin

However, that hides the changing usage pattern over the 3 years with Ektobann only becoming available in 2006 and deltamethrin in 2005. The use of cypermethrin has greatly diminished during the study period. In 2006 the estimated quantities of sea lice active ingredient were:

Teflubenzuron(177kg)>> Emamectin(6.4kg) > Deltamethrin(3.26L) >>
Cypermethrin(0.04L)

Other treatments and substances used include the anti-fungicide bronopol, the anaesthetic tricaine methane sulphonate and disinfectants.

Other substances discharged by fish farms include nitrogen, phosphorus and organic carbon associated with fish waste and feed. Antifoulants and feed are also a source of copper and zinc. A total load for feed derived zinc discharge is estimated at approximately 966kg in 2005. No priority action substances (Water Framework Directive Annex X and IX) are directly used in aquaculture.

The extent of finfish aquaculture in Ireland

The most recent information from DCMNR indicates 45 marine sites licenced for finfish aquaculture and 69 freshwater site licences. There are considerably less active sites and, as an indicative figure, the Marine Institute fish health database lists 60 finfish aquaculture sites of which 27 are marine sites.

Aquaculture: Medicine regulation and monitoring

This report includes information on the authorisation process for medicines for use in aquaculture and also on related monitoring programmes. Work is underway to develop an approach for regulating chemical use and discharge from finfish aquaculture in Ireland.

1. Introduction

1.1 *Scope of the report*

This report was prepared by Evin McGovern, Marine Institute on foot of a request by the South Western River Basin District (SWRBD). The report covers the following agreed areas

- Review of dangerous substances relevant to aquaculture
- A list of licences for fish farms and an indication of which are believed to be currently active
- Assessment of total quantities of relevant treatments prescribed for 2004- 2006
- A short overview of the regulatory system

Information presented in chapters 3, 4, and 5.1 was compiled by Hamish Rodgers, Vet-Aqua International. The figures used in these sections have been sourced from Vet-Aqua International, which is the veterinary practice that provides veterinary services to the majority (90 – 95%) of the finfish farms in Ireland and its sister company, Atlantic Veterinary Services Ltd., which is a Department of Agriculture authorised wholesaler for animal remedies. There are other agricultural suppliers of disinfectants for fish farms in Ireland and in the absence of exact figures for the supply of these to fish farms estimates have been supplied based on the treatments considered to have been undertaken by the farms. Any estimates used are based on the knowledge of the treatment or cleaning frequency on the fish farms. Fish vaccines are not included in this report.

The information contained in this report provides a current “snapshot”. However, the pattern of medicine use changes continually as new products or alternatives (e.g. vaccines) become available and other treatments become less effective. The pattern of medicine usage will also vary as new diseases emerge or as old diseases change their pattern of virulence.

1.2 *Finfish Aquaculture in Ireland*

The finfish aquaculture sector in Ireland predominantly produces Atlantic Salmon (*Salmo salar*). Rainbow trout (*Oncorhynchus mykiss*) accounts for a much smaller part of the sector and both freshwater and sea reared trout are produced.

For salmon and sea-reared trout the cycle commences in freshwater hatcheries and initial rearing occurs in freshwater before transfer to sea. Table 1 shows the production statistics for 2003 - 2005. Production has been falling since a peak in 2001 (Total volume in 2001: 25,082 tonnes of which 23,312 was salmon). In the European context, Ireland is a relatively small finfish aquaculture producer as many countries have a substantial freshwater industry. The only two other countries in Europe that are significant producers of farmed Atlantic salmon are Norway and the UK and both of these countries are much larger producers than Ireland (Norwegian, UK and Ireland production for 2005 was 582,043, 129,823 and 13,764 tonnes respectively. Source Eurostat).

Table 1: Aquaculture production in 2003 –2005 (Tonnes)¹

	2003	2004	2005
Salmon	16,347	14,067	13,764
Sea Reared Trout	370	282	717
Freshwater trout	1,081	889	897
Others	40	25	6
Total	17,838	15,263	15,384

Note, that as well as hatcheries rearing fish for intensive aquaculture production there are also freshwater hatcheries and facilities rearing fish for angling and for stocking of wild fisheries. These are not covered in this report.

¹ Parsons, A, (2005) Status of Irish Aquaculture 2004& Browne, R. (2006). Status of Irish Aquaculture (2006). Reports produced by MI Galway, BIM and Taighde Mara Teo.

1.3 Chemicals usage in aquaculture

Use of chemicals in finfish aquaculture can be grouped as follows:

- a. Medicinal treatments (these may be bath or in-feed treatments)
- b. Antifoulants used on equipment (nets, cages)
- c. Anaesthetics
- d. Feed additives (e.g. zinc, dyes)
- e. Others (e.g. Disinfectants, detergents)

Other substances are discharged in fish waste or uneaten feed, for example

- f. nutrients associated with waste,
- g. contaminants associated with feed.

No priority action substances (Water Framework Directive Annex X and IX) are directly used in aquaculture.

The primary medicinal treatments used in aquaculture are

- Antibacterial agents
- Antifungal agents
- Antiparasitic treatments (e.g. Sea lice treatments)

1.3.1 Medicines/ veterinary treatments:

A detailed review of the use of veterinary treatments is given in chapters 3 and 4. The increased use of vaccines has reduced the use of antibiotics in this sector although the use varies as different issues arise and as disease patterns vary.

Under the National Sea Lice Management Programme, measures are taken to control the levels of sea lice in farmed salmon and mitigate against possible impacts on wild sea trout stocks. An important element of the management strategy is targeted treatment regimes, included synchronous treatments.

In accordance with the residues directive (Dir. 96/23/EC), monitoring is carried out by the Marine Institute, on behalf of DCMNR, to support consumer protection (food safety), ensure proper use of medicines (e.g. adherence to withdrawal periods), and control use of illegal substances. Use of Malachite Green (MG) in freshwater has been detected in the past but, following increased surveillance and industry awareness, the results of the MI's monitoring programme suggest this practice has ceased. As MG is not a veterinary treatment it may not be used even under the cascade principle (see Chapter 5.2).

There is some uncertainty as to whether or not antibiotics and disinfectants should be considered as biocides under Directive 76/464. Antibiotics are not included in the exhaustive list of biocide products in Directive 98/8 and are not specifically mentioned in List I or II of Directive 76/464. It is also worth taking note that SEPA have not set EQSs for antibiotics used in aquaculture.

1.3.2 Feed additives & contaminants:

Zinc is added to feeds to prevent cataracts in fish and therefore finfish aquaculture is a source of zinc through uneaten feed and fish waste. The Scottish Environmental Protection Agency (SEPA) have published a method for fish farms to estimate the emissions of zinc from marine fish farms calculated from the quantity of feed used². This assumes 23% is emitted to the environment (3% loss through uneaten feed and 20% through excreta).

Applying this formula and assuming a feed conversion ratio of 1.25:1 to production statistics (table 1) to calculate total feed quantities used, it is estimated of the total load of feed derived zinc discharged in 2005 from Irish finfish aquaculture was approximately 966kg.

Feed is also a potential source of other additives and contaminants.

² SEPA (2004) Scottish Pollution research Inventory, Marine Fish Farm Emission Calculation consultation Part 2. 24 November 2004.

Organochlorine compounds such as PCBs, have been detected in the fish oil/fish meal used in feed. In a study undertaken in 2001/2, SEPA³ found levels of PCBs in sediments collected in areas close to marine fish farm cages in the concentration range 0.45 to 34.3 µg/kg. The report indicated that the majority of sites would be considered “slightly contaminated” but below “probable biological effects” levels.

Improvements in feed formulation and in fish farm practices have led to improved feed conversion ratios and reduced feed loss.

1.3.3 Antifoulants: Use of Tributyltin (TBT) has not been permitted on aquaculture installations for over 20 years. Where antifoulants are used to prevent fouling of cages they are usually, copper based. Zinc may also be an active ingredient in some products. Antifoulants are not always used and mechanical cleaning of nets/equipment is often preferred.

³ SEPA (2005). The Occurrence of Polychlorinated Biphenyls in Sediments Adjacent to Marine Fish Farms: Results of Screening Surveys During 2001 & 2002. Report TR- 030905_LJS. November 2005.

2. Overview of fish farm licences in Ireland

The fish farming industry has undergone substantial rationalisation in recent years. While a record of extant licences is maintained by DCMNR, this does not reflect the true number of active sites. The Marine Institute's fish health unit holds an indicative list of actual sites in operation, including marine and freshwater. This is based on best information available to the Marine Institute. However, this information is likely to date rapidly as the sector is subject to constant change. Currently, as an indicative number 60 sites are listed of which 27 are marine sites. In total 39 companies are listed.

3. A review of medicine and disinfectant usage in Irish finfish aquaculture 2004 –2006

The trade names, active ingredients and whether the product is used by freshwater, marine or both types of fish farms are listed in Tables 3 and 4. The percentage active ingredients in the formulations of medicines and disinfectants and the quantities used are shown in Tables 5 and 6 for the years 2004 to 2006 inclusive. The breakdown per year of the medicines and disinfectants used are shown in Tables 5 and 8. The quantities of the products and active ingredients used in freshwater or the marine farms for the three years are shown in Tables 9 and 10.

Table 3: Medicines used in finfish aquaculture (freshwater and/or marine farms) in Ireland 2004 – 2006

Medicine	Active Ingredient	Freshwater Marine/Both	Form	Treatment
Alphamax	Deltamethrin	Marine	Liquid	Bath
Betamox LA	Amoxicillin	Freshwater	Liquid	Injection
Ektobann	Teflubenzuron	Marine	Powder	Feed
Excis	Cypermethrin	Marine	Liquid	Bath
Florocol	Florfenicol	Both	Powder	Feed
Maracycline	Oxytetracycline hydrochloride	Both	Powder	Feed
MS 222	Tricaine methane sulphonate	Both	Powder	Bath
Pyceze	Bronopol	Both	Liquid	Bath
Slice	Emamectin benzoate	Both	Powder	Feed
Sulfatrim	Trimethoprim & sulphadiazine	Both	Powder	Feed

Table 4: Disinfectants used in finfish aquaculture (freshwater and/or marine farms) in Ireland 2004 – 2006

Disinfectant	Main Active Ingredient	Freshwater/ Marine Both	Form
Biosolve	Sodium hydroxide	Freshwater	Liquid
Buffodine	Iodine	Freshwater	Liquid
FAM 30	Iodine, phosphoric acid, sulphuric acid	Both	Liquid
Formalin	Formaldehyde	Freshwater	Liquid
Halamid	Sodium p-toluenesulfonchloramide (chloramine T)	Freshwater	Powder
Hydrogen peroxide	Hydrogen peroxide	Marine	Liquid
Vetrefoam	Sodium hydroxide	Freshwater	Liquid
Virkon Aquatic	Pentapotassium bis (peroxymonosulphate) bis (sulphate)	Both	Powder
Virudine	Iodine, orthophosphoric acid, sulphuric acid	Both	Liquid

Table 5: Percentage active ingredients and quantities of medicines used in finfish aquaculture in Ireland 2004 – 2006 (AR 16 – exceptional temporary license issued by Dept. of Agriculture, cascade – refers to process veterinarians may use under the Animal Remedies Regulations 2005 where there is no authorised animal remedy, MA – marketing authorisation, POM – prescription only medicine, POM (E) – prescription only exempt medicine).

Medicine	Percentage Active Ingredient	Quantity '04 – '06 (litres or kg)	Quantity active '04 – '06 (l or kg)	Authorisation status*
Alphamax	1	341	3.41	AR16
Betamox LA	15	2.4	0.36	Cascade(full MA for terrestrial animals)
Ektobann	100	177	177	AR16
Excis	1	415.2	4.15	Full MA for salmon – POM (E)
Florocol	50	45	22.5	AR16 & cascade (full MA in UK)
Maracycline	100	2,465	2,465	Full MA for salmon – POM
MS 222	100	159	159	MA pending
Pyceze	50	69	34.5	Cascade (full MA in UK)
Slice	0.2	11,865	23.7	Full MA for salmon – POM
Sulfatrim	50	98	49	License expired and medicine no longer available

**The status of all medicines is subject to change but the status of listed medicines at the time of writing is given.*

Table 6: Percentage of active ingredients and quantities of disinfectants used in finfish aquaculture in Ireland 2004 – 2006.

Disinfectant	Percentage Active Ingredient	Quantity '04 – '06 (litres or kg)	Quantity active '04 – '06 (l or kg)
Biosolve	1 - 5	75	3.75#
Buffodine	1	28	0.28
FAM 30	2.75% iodine	100	2.75
Formalin	39	2,050*	799.5*
Halamid	100	540	540
Hydrogen peroxide	35	1500	525
Vetrefoam	1 - 5	5	0.25#
Virkon Aquatic	50	2,250	1,125
Virudine	3% iodine	275	8.25

estimated quantity.

percentage active taken at 5%

Table 7: Quantities (litres or kilograms) of medicines (and active ingredients) used in finfish aquaculture in Ireland 2004 – 2006.

Medicine	Quantity of medicine			Quantity of active ingredient		
	2004	2005	2006	2004	2005	2006
Alphamax	0	14.5	326	0	0.15	3.26
Betamox LA	0	2.4	0	0	0.36	0
Ektobann	0	0	177	0	0	177
Excis	182.8	228.8	3.6	1.83	2.29	0.04
Florocol	15	17.5	12.4	7.5	8.75	6.2
Maracycline	251.5	949	1264.5	251.5	949	1264.5
MS 222	56.7	66.9	35.2	56.7	66.9	35.2
Pyceze	16	28	25	8	14	12.5
Slice	4,169	4,500	3,193	8.34	9	6.39
Sulfatrim	67	31	0	33.5	15.5	0

Table 8: Quantities (litres or kilograms) of disinfectants (and active ingredients) used in finfish aquaculture in Ireland 2004 – 2006.

<i>Disinfectant</i>	Quantity of disinfectant			Quantity of active ingredient		
	<i>2004</i>	<i>2005</i>	<i>2006</i>	<i>2004</i>	<i>2005</i>	<i>2006</i>
Biosolve	0	55	20	0	2.75	1
Buffodine	1	12	15	0	0.12	0.15
FAM 30	100	0	0	5	0	0
Formalin*	683	683	683	266.4	266.4	266.4
Halamid	210	137	193	210	137	193
Hydrogen peroxide	0	0	1500	0	0	525
Vetrefoam	0	5	0	0	0.25	0
Virkon Aquatic	40	570	1640	20	285	820
Virudine	100	105	70	3	3.15	2.1

* Estimate

Table 9: Quantities of medicines used (and active ingredients) in finfish aquaculture (freshwater and/or marine farms) in Ireland in the three years 2004 to 2006 (in litres or kilograms).

Medicine	Quantity used in freshwater (FW)	Quantity of active in FW	Quantity used in marine (SW)	Quantity of active in SW
Alphamax	0	0	341	3.41
Betamox LA	2.4	0.36	0	0
Ektobann	0	0	177	177
Excis	0	0	415.2	415.2
Florocol	8	4	37	18.5
Maracycline	105	105	2360	2360
MS 222	132	132	27	27
Pyceze	67	33.5	2	1
Slice	22.5	0.05	11842.5	23.7
Sulfatrim	18	9	80	40

Table 10: Quantities of disinfectants used (and active ingredients) in finfish aquaculture (freshwater and/or marine farms) in Ireland in the three years 2004 to 2006 (in litres or kilograms).

Disinfectant	Quantity used in freshwater (FW)	Quantity of active in FW	Quantity used in marine (SW)	Quantity of active in SW
Biosolve	75	3.75	0	0
Buffodine	28	0.28	0	0
FAM 30	40	1.1	60	1.7
Formalin*	2,050	799.5	0	0
Halamid	540	540	0	0
Hydrogen peroxide	0	0	1500	525
Vetrefoam	5	0.25	0	0
Virkon Aquatic	2220	1110	30	15
Virudine	25	0.75	245	7.35

**Estimate*

4. Use of medicines and disinfectants in finfish aquaculture & environmental toxicity data

4.1 Medicines

Alphamax

Alphamax is used for the treatment of sea lice at a treatment dosage of 0.2 to 0.3ml/m³ with the 10mg/ml formulation (2 - 3µg/litre for 30 – 40 minutes). It is used with either a tarpaulin to enclose the treatment pen or more commonly in a well-boat where the treatment volume is more easily controlled and also significantly reduced. The active ingredient is deltamethrin, a synthetic pyrethroid which is widely used in terrestrial ectoparasite control in Ireland for cattle and sheep. Deltamethrin is highly toxic for fish, the 96-h LC₅₀ ranging between 0.4 and 2.0µg/litre and is also toxic to aquatic invertebrates (48-h LC₅₀ for *Daphnia* is 5µg/litre)⁴. The product is toxic to crustaceous animals, and it is not recommended that it be used close to installations where crabs and lobsters are kept (< 200m), or where local sea currents lead to risk of exposure⁵. However, extensive field studies, in experimental ponds, and field use have shown that this high potential toxicity is not realised. Deltamethrin is not mobile in the environment because of its strong adsorption on particles, its insolubility in water, and very low rates of application.

Betamox LA

Betamox LA is a long acting injection formulation of amoxicillin trihydrate which is licensed for use in terrestrial domesticated animals where a broad spectrum antibiotic is required. It has been used occasionally in fish at risk from furunculosis by injection at the time of vaccination at a dose of 0.1ml/fish. Amoxicillin is rarely used now in aquaculture and has a very short environmental half-life (hours)⁶.

⁴ World Health Organisation (1990) Deltamethrin. Environmental Health Criteria 97. WHO, Geneva

⁵ Pharmaq (2005) Alphamax Material Data Sheet. Pharmaq, 21 November 2005

⁶ Black, K. D. (1998) The environmental interactions associated with fish culture. In: Biology of Farmed Fish (ed. by K. D. Black & A. D. Pickering). Sheffield Academic Press, Sheffield.

Ektobann

Ektobann is an oral treatment for sea lice which has recently been licensed in Ireland under an AR16. The active ingredient is teflubenzuron which was previously subject to a full marketing authorisation for the treatment of salmon under the trade name Calicide. Teflubenzuron is a benzoyl urea compound registered in many countries (including EC states) for use on a range of crops. Environmental data demonstrates that teflubenzuron is strongly adsorbed by soils and sediments and has a low potential for bioaccumulation. Studies with the use of teflubenzuron by the Scottish Environmental Protection Agency (SEPA) in salmon farms in Scotland confirmed that although measurable levels of teflubenzuron were noted at distances up to 1000m in line with the main current flow, by 645 days after the last treatment, around 98% of the total load had been degraded or dispersed from the treatment site. In addition, no adverse effects were detectable on benthic biology or site crustacea and it was concluded that by later stages residual teflubenzuron was in a non-bioavailable form⁷.

Excis

Excis is the trade name for another synthetic pyrethroid known as cypermethrin which has been used for the treatment of sea lice at the dosage of 0.5ml/m³ for 60 minutes (5µg/litre). This pyrethroid has also been widely used in terrestrial ectoparasite control, however, tolerance of sea lice to this medicine in some areas in Ireland has curtailed the use of the product, as can be seen in Table 5. Cypermethrin is very toxic for fish (96-h LC₅₀s were generally within the range of 0.4 – 2.8µg/litre in laboratory tests) and aquatic invertebrates (LC₅₀s in the range of 0.01 - 5µg/l)⁸. However, the presence of suspended solids decreases the toxicity of cypermethrin by at least a factor of 2, because of adsorption of cypermethrin to the solids.

⁷ SEPA (1999) Calicide (teflubenzuron) – authorisation for use as an in-feed sea lice treatment in marine cage salmon farms. Risk Assessment, EQS and recommendations. Policy no. 29. SEPA Fish Farming Advisory Group, SEPA, Stirling.

⁸ World Health Organisation (1989) Cypermethrin. Environmental Health Criteria 82, WHO, Geneva

Florocol

Florfenicol is the active ingredient in Florocol and this antibiotic is used occasionally as an oral medicine for systemic bacterial infections at the dosage of 10mg active/kg biomass fish/day for 10 days. Both florfenicol and its metabolites will enter the water column by leaching from medicated feed and faeces and by excretion in the aqueous phase of the excreta.

Experimental studies of the persistence in marine sediments have indicated that the concentration of florfenicol decreased rapidly in the sediment with a calculated half-life of 4.5 days⁹. The metabolite, florfenicol amine, was detected and it appears that florfenicol is rapidly degraded in sediment. In studies minimum inhibitory concentrations, LC₅₀, or EC₅₀ values and NOELs were compared to the predicted environmental concentration (PEC) in water and sediment in both marine and freshwater environments and the PEC values refined based on degradation and dissipation and values given were as follows:

Compartment	PEC value
Marine sediment	224µg/kg
Seawater	0.0035µg/litre
Freshwater	<0.0625µg/litre

The PEC to predicted no effect concentration (PNEC) ratio values were established for a range of micro-organisms, plants, invertebrates and fish and all were found to be very low reflecting the lack of toxicity of florfenicol to aquatic organisms and the rapid degradation and dissipation of the compound¹⁰.

⁹ Hektoen, H. *et al.* (1995) Persistence of antibacterial agents in marine sediments. *Aquaculture*, 133, 175 – 184.

¹⁰ Schering-Plough Animal Health (2000) *Aquaflor Technical Monograph*. SPAH, Union, NJ, USA

Maracycline

Oxytetracycline hydrochloride is the antibiotic in Maracycline which is used when required to orally treat systemic bacterial infections at the dose rate of 75 to 100mg/kg biomass/day for 10 days. This antibiotic is widely used in terrestrial medicine for humans and domestic animals. Oxytetracycline appears to have long residence times in sediments, with various half-lives reported of up to hundreds of days and trace of uptake has also been detected in oysters and crabs in close proximity to treated salmon pens in Canada¹¹. Coyne *et al.* studied the fate of oxytetracycline in sediments at an Irish fish farm at Bertraghboy Bay¹². It was reported that concentrations in sediments declined exponentially with time and were reduced to traces after 66 days. The half life in mussels was reported as approximately 2 days.

MS222

MS222 or tricaine methane sulphonate is used as a bath solution to sedate and anaesthetise fish for vaccination in freshwater and also for examination, sample weighing and lice count examinations in marine farms. It is used as a local anaesthetic in humans. It is used for fish at concentrations of 15 to 200mg/l and is rapidly absorbed through the gills. The elimination half-life in salmon muscle is 70 minutes (in freshwater) and tricaine is rapidly metabolised by the liver¹³. The compound is assumed to be biodegradable but it is recommended not to discard it into the environment¹⁴.

Pyceze

Bronopol (2-bromo-2-nitropropane-1,3-diol) is an antimicrobial preservative, which is used in human shampoos, cosmetics, in food-contact materials and also as a bath treatment for the control of fungal infections in farmed

¹¹ Fisheries & Oceans Canada (2003) A scientific review of the potential environmental effects of aquaculture in aquatic ecosystems. Volume 1. Ottawa, Canada

¹² Coyne, R., Smith, P., Moriarty, P. (2001) The fate of oxytetracycline in the marine environment of a salmon cage farm. Marine Environment and Health Series, No. 3. Marine Institute. Dublin.

¹³ EMEA (1999) Tricaine mesilate. Committee for Veterinary Medicinal Products, London, EMEA/MRL/586/99-Final April 1999.

¹⁴ Pharmaq (2001) MS222: material health and safety data sheet. January 2001, Pharmaq Ltd., Fordingbridge, UK

salmonids and eggs and for bacterial challenges in cod eggs. Dosage rates are usually 30 – 50mg bronopol/l water for 30 minutes, repeated as required (sometimes daily). Ecological information indicates 96-h LC₅₀s for rainbow trout of 20mg/litre, 48-h EC₅₀ for *Daphnia* of 1.4mg/l and 72-h EC₅₀ for freshwater algae (*Selenastrum capricornutum*) of 0.16mg/l¹⁵.

Slice

Emamectin benzoate is the active ingredient in Slice and is used at treatment levels of 50µg/kg of fish biomass per day for seven days. The available data indicate that the use of emamectin benzoate to treat lice infestations in salmon should create no risk of adverse impacts on sensitive pelagic life, vertebrate or invertebrate¹⁶. Whilst PEC: PNEC values for sediments in the vicinity of treated farms, derived from conservative models, indicate a risk to sensitive invertebrates, measured concentrations in sediments close to the farm indicate a much smaller localised risk. The environmental risk characterisation for emamectin is shown over:

Table 11: PEC and PNEC values for Emamectin benzoate in sediment

Compartment	PEC value ppb)	PNEC (ppb)	PEC:PNEC
Feed	5,000	1.11*	4,505
		6,820**	0.73
Faeces	156 – 637	1.11*	141 – 574
		6,820**	0.02 – 0.09

* derived from *Arenicola marina* exposed in sediment

** derived from *Nephrops norvegicus* exposed to medicated feed

¹⁵ Novartis (2004) Pyceze: material safety data sheet. 6th October 2004, Novartis Animal Vaccines Ltd., UK

¹⁶ Schering-Plough Animal Health (2002) Potential environmental impacts of emamectin benzoate, formulated as Slice, for salmonids. Technical Report, Union, NJ, USA.

Sulfatrim

This broad spectrum antibiotic which is a potentiated sulphonamide (trimethoprim and sulphadiazine) is now no longer available as the license has expired and the formulation for aquaculture is no longer produced by the pharmaceutical company (Novartis). Dosage rate was 30mg/kg fish/day for eight days. Trimethoprim has a short environmental half-life, however, sulphadiazine is more persistent¹⁷.

4.2 Disinfectants

Biosolve & Vetrefoam

The alkali, sodium hydroxide is the active ingredient in both of these heavy duty cleaning agents which are utilised on farms to degrease and clean equipment, boats, tanks, etc. prior to disinfection. It is corrosive and irritant and the organic components are biodegradable.

Buffodine

Buffodine is an iodine complex disinfectant for use against major fish viruses and is used for the disinfection of fish eggs. It is used as a short bath or rinse at 10 parts Buffodine to 1000 parts water and has 1% active iodine in the Buffodine.

FAM 30, Virudine and others

These iodophore disinfectants are used for farm equipment, tank, boat disinfection as well as for foot dips/baths and are corrosive and may cause long term adverse effects on the aquatic environment¹⁸. They are generally effective against pathogens in low concentrations but are inhibited in the presence of organic matter or hard water more than most disinfectants. They are one of the recommended disinfectants in the Irish infectious salmon

¹⁷ Samulesen, O. B. *et al.* (1994) Stability of antibacterial agents in an artificial marine aquaculture sediment studies under laboratory conditions. *Aquaculture*, 126, 283 – 290.

¹⁸ Antec (2004) Virudine safety data sheet HSD/37D. Antec International Ltd., Suffolk, UK

anaemia (ISA) withdrawal plan. The World Organisation for Animal Health (OIE) recommends that whenever iodine compounds are used for disinfection and are being discharged they should always be neutralised with an equivalent amount of sodium thiosulphate¹⁹, however, this is not widely practised due to the impracticality of carrying out the procedure.

Formalin

Formalin is a formaldehyde solution which is normally purchased by the farms at 37 – 39% active and then used at 150 to 250ppm for 30 to 60 minutes. Solutions at less than 100ppm are readily biodegraded and formaldehyde is not known to be significantly bioaccumulated. Formaldehyde in lake water decomposed in approximately 30 h under aerobic conditions at 20 °C and in approximately 48 h under anaerobic conditions²⁰. Half-lives of 24 – 168 h in surface water and 48 – 336 h in groundwater have been estimated. Environmental toxicity data for a wide range of terrestrial and aquatic organisms are available²¹.

Halamid

Halamid is a trade name for sodium p-toluenesulfonchloramide, otherwise known as chloramine T and is a disinfectant active against bacteria, viruses, fungi and parasites. This sodium salt slowly decomposes in water to the hypochlorite anion and hence to weak hypochlorous acid. This in turn decomposes to chlorine and oxygen. The degradation product of chloramine T is p-toluene-sulfonamide (pTSA)²². There are results for toxicity testing on a range of aquatic species such as *Daphnia magna* (48 hour NOEC 1.8mg/l) and *Pimephales promelas* (35 day NOEC 1.5mg/l)²³. It is used in freshwater at dosages from 2 to 20ppm for up to 60 minutes.

¹⁹ OIE (2003) Manual of Diagnostic Tests for Aquatic Animals, 4th Edition. OIE, Paris

²⁰ World Health Organisation (2002) Formaldehyde. Concise International Chemical Assessment Document 40. WHO, Geneva.

²¹ World Health Organisation (2002) Formaldehyde. Concise International Chemical Assessment Document 40. WHO, Geneva.

²² Treves-Brown, K. M. (2000) Applied Fish Pharmacology. Kluwer Academic Publishers, Dordrecht

²³ Campbell, D. J. C. & Parsons, D. G. (1999) Halamid = Biosecurity. Fish Veterinary Journal, 3, 68 – 73.

Hydrogen peroxide

Hydrogen peroxide has many industrial uses as a bleaching and oxidising agent, however, there is a renewed interest in its use versus sea lice in salmon and as a disinfectant. Where it has been used as such the dosage is usually 1500ppm for up to 20 minutes. In the absence of a stabilising agent hydrogen peroxide rapidly decomposes to oxygen and water. Although hydrogen peroxide is toxic to some aquatic organisms including marine phytoplankton and crustacean, the rates of dilution and dissociation encountered on fish farms ensure that harmful effects on the environment are minimised²⁴.

Virkon Aquatic

Virkon Aquatic is used at 0.2 to 1% for at least 10 minutes and ecotoxicology data is available for fish and invertebrates (*Salmo salar* 96-h LC₅₀ 24.6ppm, post-larvae tiger prawns 96-h LC₅₀ 10.31ppm, goldfish 48-h LC₅₀ 500mg/l, *Daphnia magna* 48-h EC₅₀ 6.5mg/l)²⁵.

²⁴ EMEA (1996) Hydrogen peroxide. Committee for Veterinary Medicinal Products, EMEA/MRL/061/96-Final, February 1996.

²⁵ Antec (no date) Antec Virkon (S) ecotoxicology summary. Safety data sheet. Antec International, Suffolk.

5. Finfish aquaculture regulation

5.1 Overview of fish medicine licensing in Ireland

The supply and use of medicines in Ireland is governed by the Animal Remedies Regulations 2005 (S. I. no. 734 of 2005) which were made under the Animal Remedies Act, 1993. Any product that claims a medical benefit for an animal must be assessed, registered and issued with a marketing authorisation (Veterinary Product Authorisation or VPA) by the Irish Medicines Board (IMB). Authorised medicines are prescribed for use on a case by case basis by a vet who may apply the veterinary cascade provisions, which itself can lead to problems with extended withdrawal periods, difficulties in importing products and extensive paperwork. In Ireland there are very few fully authorised medicines for salmon (four). There are no authorised medicines for trout, cod, perch or char so all these species have to be treated under the cascade. The few medicines that are available for salmon may be ineffective due to bacterial resistance or parasitic tolerance and hence special applications require to be made to the Department of Agriculture to allow the exceptional use of medicines available in other countries (the AR16 license), although for food-producing animals (as most farmed fish are classified) only products with an established maximum residue limit (MRL) which is classified at EC level can be used. Pharmaceutical companies may have to spend many millions of euro to have a medicine licensed in a country for a specific species and there is an increasing reluctance to invest in this process at present. Licenses require to be maintained (which costs money) and even though temporary AR16 licences may be issued by the Department of Agriculture in emergency or special case situations (for named farms), these are issued on the understanding that further applications will be made for full license.

5.2 **Monitoring of aquaculture in Ireland**

Residues Monitoring (Directive 96/23/EC)²⁶: In accordance with this directive, salmon and trout from fish farms are routinely monitored for the presence of veterinary residues, contaminants and other substances. The purpose is to support consumer protection (food safety), ensure proper use of medicines (e.g. adherence to withdrawal periods), and control use of illegal substances. This legislation and monitoring does not deal with broader environmental issues that may be associated with use of treatments. Monitoring is carried out by the Marine Institute on behalf of DCMNR and in liaison with FSAI. Annual residue control plans are agreed by DCMNR, MI and FSAI. The Department of Agriculture and Food (DAF) compile the National Animal Residues Control Plan for transmission to the EU. The sampling strategy depends on the substance. Primarily fish are sampled at harvest to ensure that levels of authorised medicines do not exceed Maximum Residue Levels (MRLs). However, fish are also sampled at other stages of production to target illegal substances such as malachite green. A summary of the outcome of recent residue monitoring is presented in table 12 showing generally good and improving compliance by the finfish aquaculture sector.

Benthic Monitoring: The Marine Institute compiles annual reviews of benthic monitoring at finfish aquaculture sites²⁷. Finfish farms subject to such monitoring must submit annual returns as a requirement of their licence. Between 2003-2005 all surveyed sites had conditions that were deemed acceptable as per the monitoring protocols. However reporting was incomplete at 54%, 56% and 66% for the years 2003, 2004 and 2005 respectively.

²⁶ Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC. *Official Journal L 125*, 23/05/1996 p. 0010 - 0032

²⁷ Parsons, A. (2005) Status of Irish Aquaculture 2004 & Browne, R. (2006). Status of Irish Aquaculture (2006). Reports produced by MI Galway, BIM and Taighde Mara Teo.

Water Column Monitoring: The majority of fish farm operators are obliged to submit reports of annual nutrient monitoring surveys, carried out monthly during the period December – March, to the Coastal Zone Management Division of DCMNR. Water samples for nutrient analysis are taken at each station along an agreed transect. Samples are taken at the surface, mid-depth and 1m above the bottom and analysis include ammonia, nitrite, nitrate and phosphate. Water temperature and salinity are also measured. The values obtained are compared against background levels found at control sites. The control site is selected at a sufficient distance away from the fish cages and deemed to be outside the influence of the fish farming activities.

Table 12: Summary results for surveillance residue monitoring in finfish aquaculture (2003-2006#)

Substances		Year	Number Non-compliant results / number of tests (no. samples)	Information on Non compliant
<u>GROUP A</u> Steroids Beta- agonists Chloramphenicol Nitrofurans	<u>GROUP B Cont'd</u> Others PCBs Organochlorine pesticides Lead Cadmium Mercury Aflatoxin Malachite green Leuco Malachite Green	2003	13/ >1000 (202)*	9 MG/ LMG ^p 4 Oxytetracycline
<u>GROUP B</u> Antibiotics Oxytetracycline Oxolinic Acid Flumequine Sarafloxacin		2004	8/ 900 (183)*	8 MG/LMG
Sea lice treatments Ivermectin Emamectin benzoate Cypermethrin Teflubenzuron Diflubenzuron		2005	2/ 731 (181)*	2 Emamectin
		2006	0/ 729 (168*)	No non-compliant results

* The numbers presented are number of non-compliant results/the number of tests carried out (number of fish samples actually tested as). Note that multiple tests are often carried out on individual samples and some tests are for multiple parameters

^p MG/LMG = Malachite Green/ leuco-malachite green

6. Conclusions

- No priority action substances (Water Framework Directive Annex X and IX) are directly used in aquaculture.
- There are a range of substances used in finfish aquaculture including veterinary medicines (primarily antibiotics, and sea lice treatments), disinfectants (mostly freshwater except hydrogen peroxide), feed additives and contaminants, antifoulants and nutrients associated with aquaculture waste. Currently the medicine used in the greatest quantity as active ingredient is the antibiotic oxytetracycline. The sea lice treatment used in the greatest quantity as active ingredient is teflubenzuron. It is not clear to the authors whether antibiotics and disinfectants are covered under the dangerous substance directive (DSD) but it is noted that SEPA have not set Environmental Quality Standards for antibiotics with respect to aquaculture. The pattern of medicine use in aquaculture is constantly changing.
- Although there are many more licensed sites, as an indicative number the Marine Institute Fish Health database currently lists 60 active sites of which 27 are marine. Again this is subject to frequent change.
- The process for authorisation of medicines is complex. Residues and benthic monitoring activities are outlined in this report and work is underway to develop a national approach for regulating chemical use and discharge for finfish aquaculture in Ireland.