

Use of Antibiotics in Norwegian Aquaculture



Veterinærinstituttet
Norwegian Veterinary Institute



Report from The Norwegian Veterinary Institute

**Use of Antibiotics in Norwegian Aquaculture
on behalf of Norwegian Seafood Council**

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Executive summary

Use of antibiotics in food production in Norway is strictly regulated through pharmacy sales and prescriptions only by veterinarians and aqua medicine biologists. Norwegian farmed fish production was app. 1,3 million tonnes in 2014, and the total amount of antibiotics to farmed fish was 511 kg based on purchase statistics (523 kg based on prescriptions issued). Only 11 of the 132 prescriptions issued were aimed at salmonid production and ten of these were for prescribed for fish at 0.1-0.4 kg bodyweight. One was prescribed for a population with an average weight of 2.1 kg. The consumption of antibiotics for salmonid production was 523,4 kg for 2014. The consumption the last eight years for salmon has been around 1 mg/kg produced fish, with 0.36 mg/kg in 2014.

The consumption of antimicrobials in Norwegian aquaculture implies a very low probability of any development of antimicrobial resistance in farmed fish and transmission of such resistance to humans. Consequently, intake of farmed fish cultivated in Norway pose a negligible risk to human health in terms of antimicrobial resistance.

Due to the low sales, it is unlikely that any new antibacterial veterinary medical products will be marketed for farmed fish in Norway in a foreseeable future.

Production of farmed fish in Norway

The production of farmed fish in Norwegian aquaculture is increasing steadily and has continued to be dominated by Atlantic salmon (Table 1).

Table 1. Production volume (tonnes) of farmed fish species in Norwegian aquaculture during the time period 2010-2014. *Data provided by the Norwegian Directorate of Fisheries (updated by 12.06.2015).*

Year	Atlantic salmon	Rainbow trout	Cod	Halibut ¹	Other species ²
2010	939 575	54 451	21 240	1 610	748
2011	1 064 868	58 472	15 273	2 767	513
2012	1 232 095	70 364	10 033	1 741	581
2013	1 168 324	71 449	3 770	1 385	472
2014 ³	1 272 358	68 954	1 386	1 257	497

¹ Numbers in 1,000 individuals; ² Mainly Arctic char, turbot and wolffish; ³ Preliminary numbers

Threshold values, medicines residues - EU

In Norway, all veterinary medicinal products (VMPs) including VMPs for use in farmed fish, are by prescription only.

Through the European Economic Agreement (EEA) Norway is committed to comply with the Council Regulation (EC) No 410/2009 of 6 May 2009 laying down Community procedures for the establishment of maximum residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 2004 of the European Parliament and of the Council.

The European Union (EU) requires by law that foodstuffs, such as meat, milk or eggs, obtained from animals treated with veterinary medicines or exposed to biocidal products used in animal husbandry must not contain residue that might represent a hazard to the health of the consumer. The maximum residue limit (MRL) is the maximum concentration of residue accepted by the EU in a food product obtained from an animal that has received a veterinary medicine. Before a veterinary medicine intended for food-producing animals can be authorised in the EU, the safety of its pharmacologically active substances and their residues must first be evaluated.

The assessment of the safety of residues is carried out by the by the European Medicines Agency's Committee for Medicinal Products for Veterinary Use (CVMP).

Once the substances have been assessed and following the adoption of a Commission Regulation confirming the classification of the substances, the substances that may be used are listed in table 1 of the annex to [Commission Regulation \(EU\) No 37/2010](#).

Some substances are considered to represent a hazard to the safety of the consumer at any level. These substances must not be used in veterinary medicines for use in food producing animals or in biocidal products for use in animal husbandry, and are included in table 2 (prohibited substances) of the annex to [Commission Regulation \(EU\) No 37/2010](#).

Detailed information on the assessment following the publication of the Commission Regulation is published on the European Medicines Agency's web pages [European public MRL assessment report](#) which is the source for the MRL- classification for the substance given in Tables 2-4.

Harmonization threshold values (MRLs) - EU/EEA countries and Codex Alimentarius

The Codex Alimentarius (or Food code) was created by the World Health Organisation (WHO) and the UN's Food and Agriculture Organisation (FAO) in 1963 to implement their Joint Food Standards Programme aimed at protecting the health of consumers, ensuring fair trade practices in the food trade and promoting coordination of all food standards work undertaken by governmental and international organizations. It lays down food health standards that serve as a reference for international trade in foodstuffs.

The main aims of the Codex are to define international standards, codes of practice and other guidelines and recommendations concerning among others, the residues of veterinary medicinal products.

Since 1994 and the entry into force of the WTO Agreements on Sanitary and Phytosanitary Measures (SPS Agreement) and on Technical Barriers to Trade (TBT Agreement), the legal relevance of the Codex standards has increased. These two Agreements make reference to those standards, meaning that the latter are used as the basis for the evaluation of national measures and regulations.

At present, all Member States of the European Union (EU) and since the end of 2003, the European Community as such is member of the Codex Alimentarius Commission, which is the body in charge of updating the Codex.

According to the Agreement on the Application of Sanitary and Phytosanitary Measures (SPM) and Agreement on Technical Barriers to Trade food safety standards for veterinary drug residues established by the Codex Alimentarius Commission are the reference points in international trade. Thus far, Codex established MRLs for about 50 veterinary drugs. Once accepted, member states of Codex are expected to implement these MRLs in national (or

community) law. Deviations from Codex MRLs are possible but have to be substantiated with scientific proof of risk (<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1439895896442&uri=URISERV:f84006>).

Article 14 of Regulation (EC) 470/2009 foresees that the European Commission adopts MRLs established by Codex provided that such MRLs were objected to by the Community Delegation.

Consumption of antibacterial agents in Norwegian aquaculture

In Norway, veterinary medicinal products (VMPs) including VMPs for use in farmed fish have as a general rule to be dispensed through pharmacies that obtain the VMPs from wholesalers. In addition, wholesalers and feed mills may dispense VMPs and feeding-stuff containing VMPs to the farmers (prescription only).

The Norwegian wholesalers and feed mills are mandated to report their sales to pharmacies and farmers to the Norwegian Public Health Institute (NPHI) that annually publish data on sales of VMPs for use in farmed fish (http://www.fhi.no/eway/default.aspx?pid=239&trg=Content_6496&Main_6157=6263:0:25,6201&MainContent_6263=6496:0:25,6205&Content_6496=6178:114175:25,6205:0:6562:1:::0:0).

The Veterinary Medicines Register (VetReg) was launched by the Norwegian Food Safety Authority 1 January 2011 and as a first step, information for each prescription issued/dispensed of VMPs for use in farmed fish was collected. From VetReg it is possible to e.g. extract data on antimicrobial consumption per fish species, production stage etc.

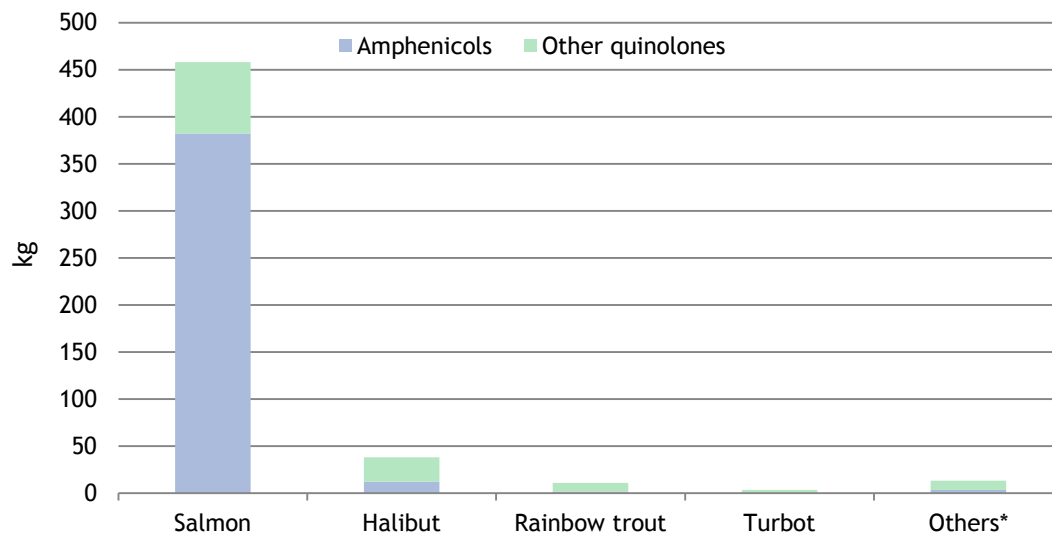
Profile of antibiotics used in Norwegian aquaculture

For 2014, prescription data (dispensed amounts) of antibacterial agents for farmed fish obtained from VetReg have been validated against sales data published by NIPH. The data consisted of N= 132 prescriptions and the prescribed amounts accounted for 523 kg which corresponds very well to sales data obtained from NIPH (Table 2: 511 kg). The prescribed amounts (kg) per fish species and antibacterial class are shown in Figure 1. For salmon, the amount prescribed during 2014 was in total 523,4 kg active substance corresponds to 0.36 mg/1 kg produced salmon.

The major part of treatments occurs during the early production stages (see Figure 2). Only 11% (n=14) of the prescriptions for on-growers were for salmon. Ten of the 11 prescriptions for salmon on-growers were for fish ranging from 0.1-0.4 kg bodyweight while one was for fish

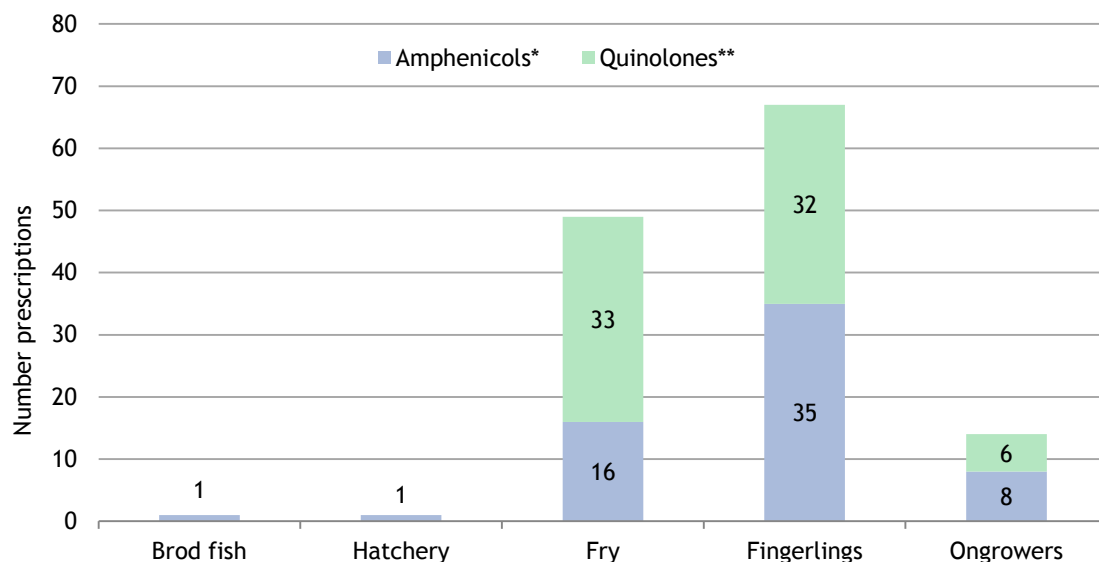
with average weight of 2.1 kg. The other three prescriptions for on-growers were for halibut, turbot and wolffish. For the 14 prescriptions for on-growers, bacterial infection was given as diagnose for 12; one prescription was for wolffish and one for turbot and the diagnosis given was furunculosis and “winter sores”, respectively. The prescribed amounts (kg), stratified by production stage, is shown in Figure 3.

Figure 1 . Amounts (kg active substance) of antibacterial agents prescribed per fish species for 2014.
Data from the Norwegian Food Safety Authority



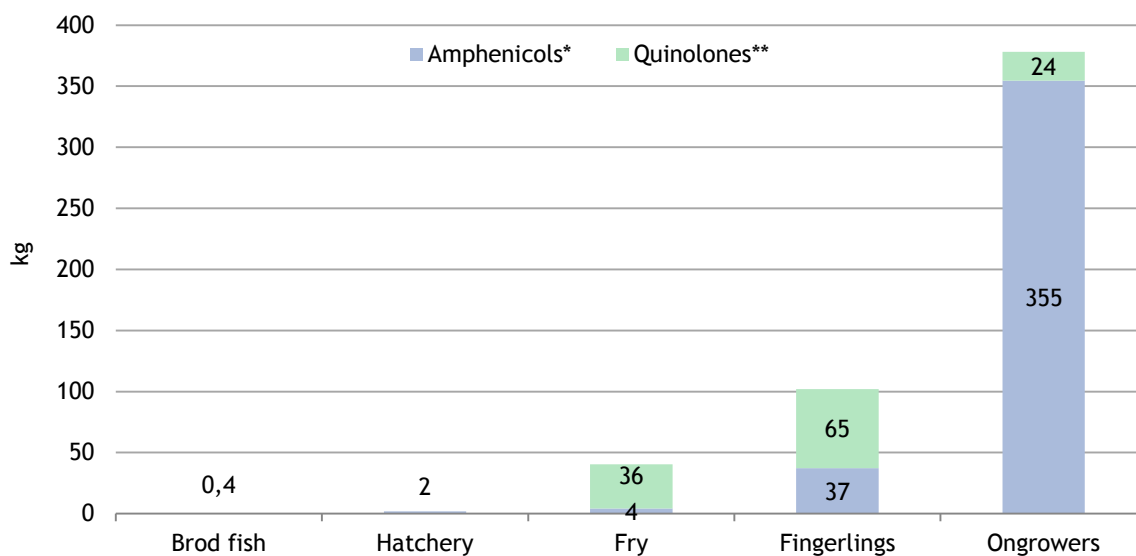
* Florfenicol; ** Oxolinic acid; one prescription flumequine (for fry) not reported to NFHI; *** Not specified

Figure 2. Number of antibacterial agent prescriptions in 2014, given by production stage. Data from the Norwegian Food Safety Authority



* Florfenicol; ** Oxolinic acid; one prescription flumequine (fry).

Figure 3. Prescribed amounts (kg active substance) of antibacterial agents per production stage of salmon in 2014. Data from the Norwegian Food Safety Authority



* Florfenicol; ** Oxolinic acid; one prescription for flumequine (fry)

The sales data of antibacterial agents for use in farmed fish for 2010-2014 are shown in Table 2.

Table 2. Sales of antimicrobial agents (in kg of active ingredients) for farmed fish in Norway and their MRL - status for farmed fish in EU/EEA countries and by Codex. Data on sales were obtained from the Norwegian Public Health Institute. Assessments reports EU/EEA MRLs: European public MRL assessment report

Class	Substance/ Products	EU/EEA MRL	Codex MRL	2010	2011	2012	2013	2014
Tetracyclines	Oxytetracycline ¹	Yes	No	10	1	1	0	0
Amphenicols	Florfenicol Floraqpharma® vet.	Yes	No	287	331	191	300	403
Quinolones	Oxolinic acid Oxolinsyre® vet	Yes	No	308	212	1 399	672	108
Other antibacterials	Lincomycin combined with spectinomycin (1:2)	Yes Yes	No No	57	0	0	0	0

¹Due to minor use medicated feed is produced case by case following prescription (*ex tempore*) from pure drug substance (concentration 100%). This product is not given a brand name.

The production volume of farmed fish together with the sales of antimicrobial agents for use in farmed fish in Norway since 1981, are shown in Figure 4. Figures 5A and 5B give a more detailed depiction of the consumption of antimicrobial agents during the same period. From Figure 5B we see that the consumption of antibacterial agents the last 8 years has been on average been below 1 mg/kg and for 2014 was down to 0.36 mg/kg fish produced.

Figure 4. Total sales, in tonnes of active substance, of antimicrobial veterinary medicinal products (VMPs) for therapeutic use in farmed fish in Norway in the period 1981-2014 versus produced biomass (slaughtered) farmed fish.

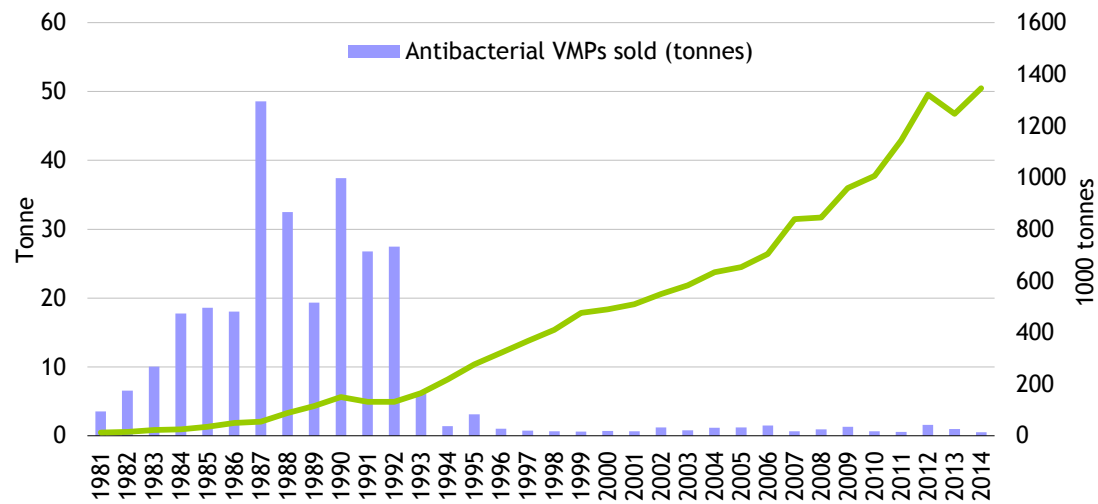


Figure 5A. Milligram antibacterial agents used per kilo fish produced during 1981-1993

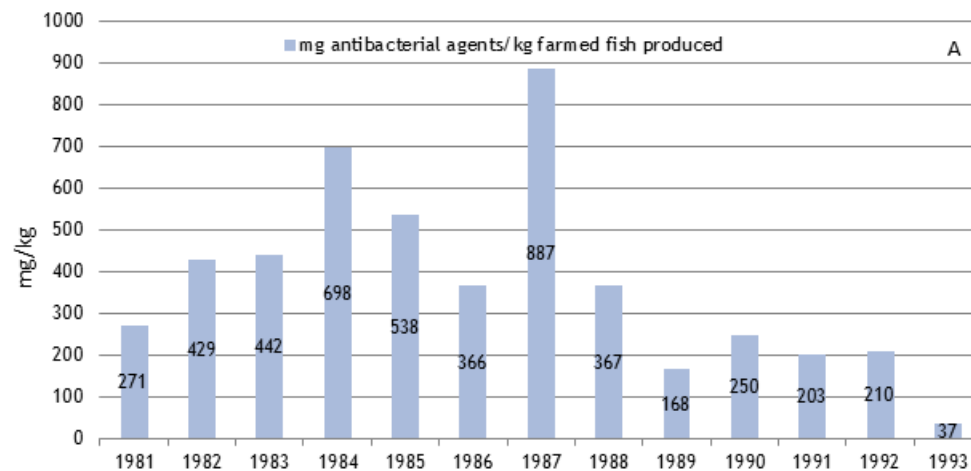
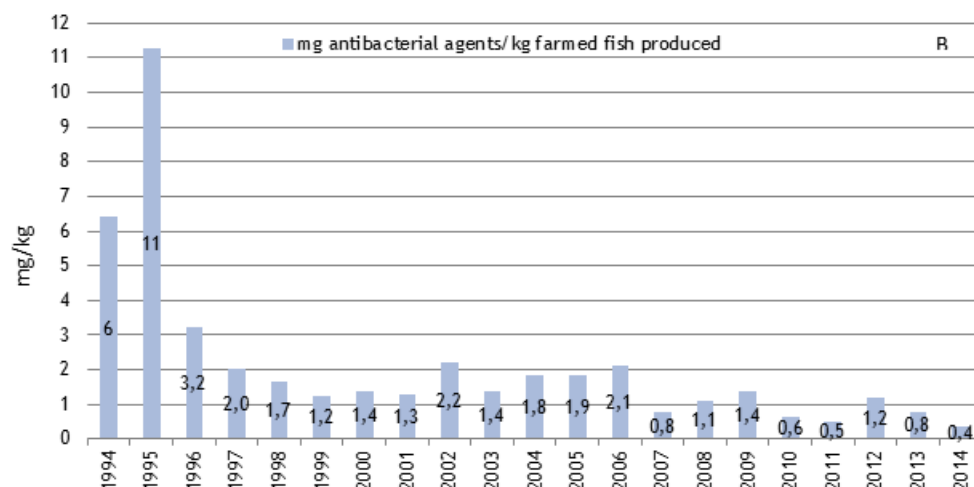


Figure 5B. Milligram antibacterial agents used per kilo fish produced during 1994-2014 (please note the different scale of the Y-axis from Figure 5A)



Comments on the current status of antibiotic use

Farmed (industrialized) production of aquatic animals is in a global perspective, difficult without the availability of antibiotic agents. Norway experienced this especially in an early stage of the development of the industry, with several severe bacterial diseases affecting the farmed salmonid population. Focus on vaccine research that quickly resulted in effective vaccines against bacterial diseases, strict biosecurity and regulatory requirements have supported a successful increase in production with almost no use of antibiotic agents. This is unique in global aquaculture.

All use of antibiotics in Norwegian aquaculture is strictly regulated by law, and only veterinarians and aquamedicine biologist can prescribe antibiotics for use to treat clinical diagnosed infectious diseases. In addition, antibiotics are only sold through pharmacies and all sales are monitored by the government.

Reduced susceptibility to antibiotic agents has become a major threat to human health. WHO has estimated that between 60-80% of all antibiotics worldwide are used in the total food production, and this use of antibiotics obviously plays a role in enhancing the global development of antibiotic resistant bacteria. The successful control of bacterial infections in Norwegian salmonid production without antibiotics is therefore an important contribution to show it is possible to be global actor in seafood production with negligible risk to human health in terms of promoting antibiotic resistant bacteria.

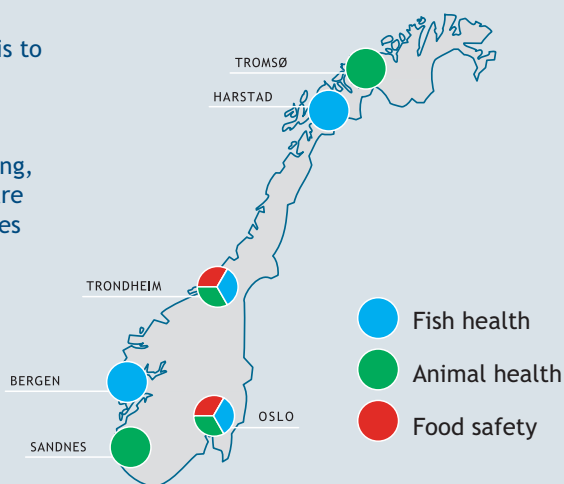
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