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Use of therapeutic agents against salmon lice in Norwegian Aquaculture

Veterinærinstituttet
Norwegian Veterinary Institute

Report from The Norwegian Veterinary Institute

Use of chemical agents against salmon lice in Norwegian Aquaculture on behalf of Norwegian Seafood Council

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Executive summary

Salmon lice is currently one of the biggest challenges to the salmon production in Norway. This is mainly due to the increasing occurrence of resistance in salmon lice to the available agents used for treatment. Chitin synthesis inhibitors (Diflubenzuron), organophosphorous compounds (Azamethiphos) and hydrogen peroxide are the chemical agents most frequently used. An increasing problem with resistance against the most commonly used agents have push forward interest and research on non-medical treatment and prevention. There are few new products in the pipeline to take over the agents currently in use.

Production of farmed fish

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 wolfish; [3] Preliminary numbers

Threshold values, medicine residues – EU

In Norway, 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 or 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.

Medicinal products for treatment against salmon lice

The sales data of anti-salmon lice products for use in farmed Atlantic salmon for 2010-2014 are shown in Table 2.

Recently, two new substances have been assigned an MRL for fin fish: lufenuron (oral) and hexaflumuron (bath treatment), both belong to the chitin synthesis inhibitors. VMPs for fish containing these substances have not yet been marketed in EU/EEA countries.

Table 2. Sales, in kg active substance, of substances for treatment against salmon lice and their MRL – status for farmed fish in EU/EEA countries and by Codex. Note that for hydrogen peroxide the sales are in (metric) tonnes. Data on sales were obtained from the Norwegian Public Health Institute. **Assessments reports EU/EEA MRLs:** European public MRL assessment report

Class	Substance/ Product name	EU/EEA MRL	Codex MRL	2010	2011	2012	2013	2014
Pyrethroids	Cypermethrin Betamax® vet.	Yes	No	107	48	232	211	162
	Deltamethrin Alpha max® vet	Yes	No	61	54	121	136	158
Organophosphorous compounds	Azamethiphos Azasure® Vet Salmosan® Vet	MRL not required[1]	No	3 346	2 437	4 059	3 037	4 630
Chitin synthesis inhibitors	Diflubenzuron Releeze® vet	Yes	No	1 839	704	1 611	3 264	5 016
	Teflubenzuron Ektobann® Vet	Yes	No	1 080	26	751	1 704	2 674
Avermectins	Emamectin* Slice® Vet	Yes	Yes	22	105	36	51	172
Others	Hydrogen peroxide (tonnes) Hydrogenperoksid Akzo Nobel Pulp and Performance Chemical AB® Paramove®	MRL not required[2]		3 071	3 144	2 538	8 262	31 577

* Same value for EU and Codex

[1] http://www.ema.europa.eu/docs/en_GB/document_library/Maximum_Residue_Limits_-_Report/2012/06/WC500128440.pdf
[2] http://www.ema.europa.eu/docs/en_GB/document_library/Maximum_Residue_Limits_-_Report/2009/11/WC500014426.pdf

Comments to the salmon lice treatments

Salmon lice is currently one of the biggest challenges to the salmon production in Norway. This is mainly due to the increasing occurrence of resistance in salmon lice to the available agents used for treatment. As mentioned, a few new products for treatment are in the pipeline. The industry has however, increased its focus on non-chemical treatment and mechanical prevention. These approaches are important for future success in controlling salmon lice.

As with antibiotics, treatment against salmon lice is initiated by veterinarians and aqua medicine biologists. There is a close follow up on such treatments and the chemical used are of no concern for human health.

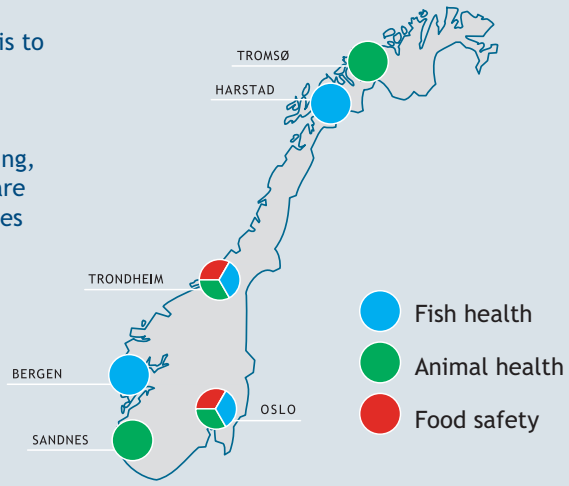
Scientifically ambitious, forward-looking and cooperatively oriented – for integrated health

The Norwegian Veterinary Institute is a national research institute that operates in the fields of animal and fish health, food safety and feed hygiene; its primary task is to provide the authorities with independently generated knowledge.

Emergency preparedness, diagnostic services, monitoring, reference functions, consulting, and risk assessments are all important areas of activity. Our products and services include research results and reports, analyses and diagnoses, studies and advice.

The Norwegian Veterinary Institute's central laboratory and administration lie in Oslo, and we operate regional laboratories in Sandnes, Bergen, Trondheim, Harstad and Tromsø.

The Norwegian Veterinary Institute collaborates with a large number of national and international institutions.



Fish health

Animal health

Food safety

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