ECONEA®
CLEAN NETS FOR HEALTHY FISH

Steen-Hansen

HOW TO RECONCILE CLEAN AQUACULTURE NETS AND FISH WELFARE WITH A CLEAN ENVIRONMENT

NEED FOR A HOLISTIC APPROACH

THE BIOFOULING PROBLEM IN MARICULTURE OF FINFISH AND POSSIBLE APPROACHES

JANSSEN PMP
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WHITEPAPER

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JANSSEN PMP, INVENTORS OF ECONEA®

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Janssen PMP is the Preservation and Material Protection division of Janssen Pharmaceutica N.V..

Janssen PMP is active in Crop Management and Microbial Control. In the Microbial Control area, Janssen PMP supplies biocides or antimicrobials used in a wide range of applications, including marine biofouling control.

Janssen has a global presence. Its headquarters and primary warehouse are located in Belgium, but Janssen PMP also has offices and a warehouse in the US and offices in Singapore.

Janssen PMP is a truly global and diverse organisation with many nationalities and with an equal representation of men and women.

Janssen PMP develops impactful, sustainable and end-to-end innovation.

We create together, connected by science.

ECONEA

ECONEA® is a metal-free marine antifouling agent for use in antifouling coatings for ship hulls, aquaculture net cages and other marine structures. ECONEA® exhibits potent, broad-spectrum activity against hard-shelled and soft-bodied invertebrate animal fouling organisms, including but not limited to barnacles, mussels, tube worms, hydroids, bryozoans and tunicates. The chemical and physical stability of ECONEA® in coatings, combined with its low solubility and leachability in water, makes ECONEA® highly durable with a long-lasting antifouling effect.

Once ECONEA® has exerted its antifouling effect and has been released from a coated net, it is very rapidly broken down, mainly through hydrolysis and photolysis.

In recognition of its environmental attributes, ECONEA® was nominated for the 2010 European Business Awards for the Environment organized by the Directorate-General of the European Commission.

GROWING IMPORTANCE OF MARICULTURE OF FINFISH

Sea-based farming of finfish has become more important than ever at a global level, and is expected to continue to grow. As presented in Figure 1, world mariculture of finfish species with sea cages is dominated by China, plus Norway and Chile (endowed with large areas of fjords protected from rough sea). Atlantic salmon is representative of sea cage culture of coldwater species, while finfish produced by sea cage farmers in China are mostly warmwater species and their composition is more diverse.

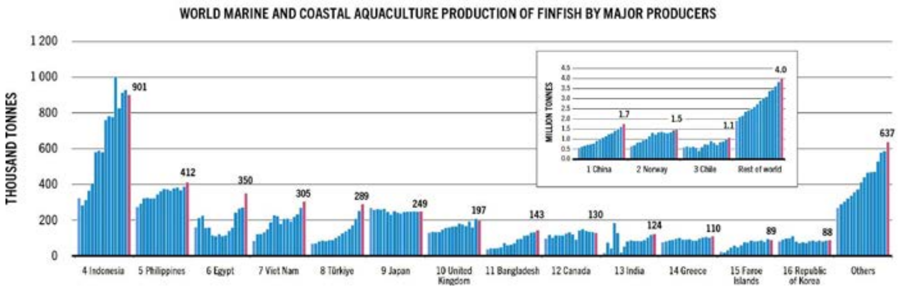
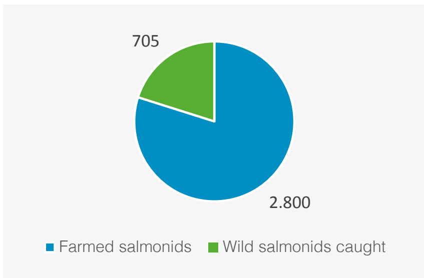


Figure 1: World marine and coastal aquaculture production of finfish by major producers, 2005 – 2020[1]

Since it started in the 1960s, the farmed salmon industry has grown substantially in the past decades, and today approximately 80% of salmonids produced worldwide are farmed. In 2021, more than 2.8 million tonnes of farmed salmonids were produced. In comparison, only around 705,000 tonnes of wild salmonids were caught[2].

Figure 2: World salmonid production in 2021 (Thousand tonnes)



Although this white paper focuses on biofouling management in salmon farming in Norway, Scotland and Chile, and the production of seabass and seabream in Turkey and Greece, many of the challenges associated with biofouling are shared and suggested biofouling management strategies may also apply to mariculture of a wider range of finfish species in other countries.

BIOFOULING SPECIES

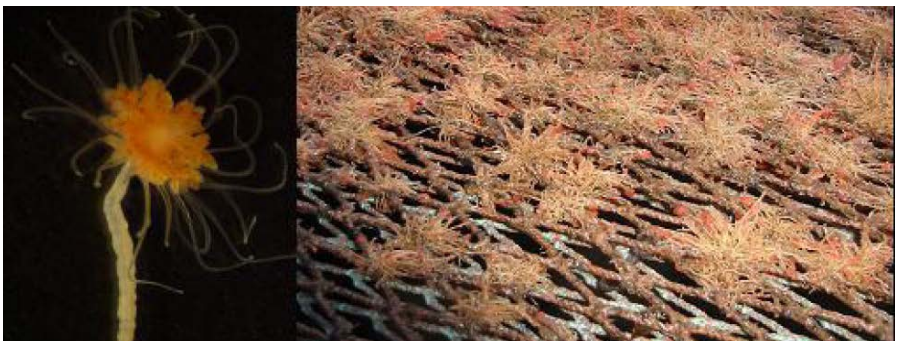
Marine biofouling, the unwanted growth of aquatic organisms on submerged structures, poses a serious problem to the aquaculture industry.

Fouling can take many different forms and shapes. The most common and problematic fouling species that are present on aquaculture equipment used in salmon farming in Norway, Scotland and Chile are summarised in **Table 1** and **Table 2**.

Table 1 Most important fouling species in salmon farms in Norway and Scotland[3,4]

Mussels	**Amphipods**	**Hydroids**
Main species:	Main species:	Main species:
Blue mussel (*Mytilus edulis*)	Skeleton shrimp (*Caprella* spp.) Scud (*Jassa* spp.)	Flowerhead polyp (*Ectopleura larynx*)
Bryozoa	**Sea squirts**	**Algae / seaweed**
Main species:	Main species:	Main species:
Crisia eburnea, Scrupocellaria scruposa	Yellow sea squirt, sea vase (*Ciona intestinalis*) Carpet seasquirt (*Didemnum vexillum*) European sea squirt (*Ascidiella aspersa*)	Green algae: *Cladophora rupestris*, *Spongomorpha* spp., sea lettuce (*Ulva lactuca*) Brown algae: *Pylaiella littoralis*, *Ectocarpus siliculosus*, *Scytosiphon lomentaria* Red algae: *Ceramium* spp., *Polysiphonia* spp.

The flowerhead polyp *(Ectopleura larynx)* is one of the most common and troublesome fouling organisms on salmon aquaculture cages in Norway and Scotland. Flowerhead polyp can be difficult to eradicate once it is established. It can regenerate itself and if it is removed using high pressure cleaning, the stalk and head will grow back within 5 to 10 days.



The hydroid *Ectopleura larynx* on nets. Photo: SINTEF

Table 2 Most important fouling species in salmon farms in Chile[5]

Mussels	**Amphipods**	**Hydroids**
Main species:	Main species:	Main species:
Chilean blue mussel (*Mytilus chilensis*)	Skeleton shrimp (*Caprella* spp.)	*Obelia* spp.
Ribbed mussel (*Aulacomya atra*)	Scud (*Jassa* spp.)	
Bryozoa	**Sea squirts**	**Algae / seaweed**
Main species:	Main species:	Main species:
Membranipora spp.	Yellow sea squirt, sea vase (*Ciona intestinalis*)	Green algae: sea lettuce (*Ulva* spp.), hollow green weed (*Enteromorpha* spp.)
Sea Mat (*Bugula* spp.)		Red algae: *Polysiphonia* spp.
		Pennate diatoms

The predominant fouling species in seabass and seabream farms in Turkey and Greece are summarised in **Table 3**.

Table 3 Most important fouling species in seabass and seabream farms in Turkey and Greece[6,7]

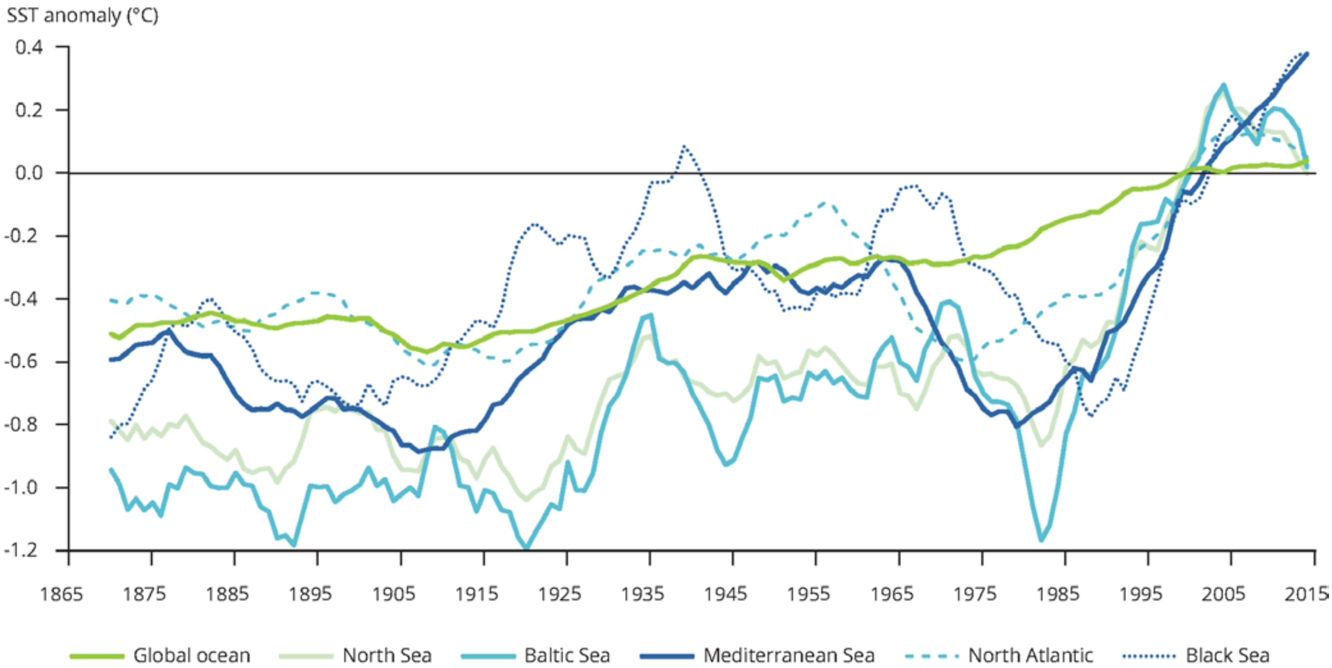
Mussels	**Polychaeta**	**Hydroids**
Main species:	Main species:	Main species:
Mediterranean mussel *(Mytilus galloprovincialis)*	Keelworm (*Pomatoceros triqueter*)	*Obelia* spp., *Tubularia* spp., *Eudentrium* spp.
	Feather duster worm (*Sabella spallanzanii*)	
Bryozoa	**Sea squirts**	**Algae / seaweed**
Main species:	Main species:	Main species:
Branching bryozoan *(Schizoporella errata)*	Yellow sea squirt, sea vase *(Ciona intestinalis)*	Green algae: sea lettuce (*Ulva* spp.), hollow green weed (*Enteromorpha* spp.)
	European sea squirt *(Ascidiella aspersa)*	Brown algae: *Dictyota dichotoma*, *Ectocarpus* spp.
		Red algae: *Polysiphonia* spp., *Ceramium* spp.

Given the static nature of aquaculture net pens, in a coastal, nutrient-rich environment and further aggravated by nutrient input of feed and faeces of stocked fish, the accumulation of fouling biomass on nets can become enormous.

INCREASING SEA TEMPERATURES AND FOULING

As the annual average sea surface temperature is rising[8], the fouling problem is getting worse over time.

Figure 3: Time series of annual average sea surface temperature (°C), referenced to the average temperature between 1993 and 2012, in the global ocean and in each of the European seas



CONSEQUENCES OF BIOFOULING ON NETS

If uncontrolled, biofouling of net pens has a negative impact on fish health and welfare for several reasons.

Net occlusion and reduced water exchange

Occlusion of aquaculture net cages due to biofouling hinders water exchange, reducing waste removal and availability of oxygen, which ultimately impacts the health, well-being, susceptibility to diseases and growth rate of the fish. The presence of biofouling also increases drag forces on the net, reducing the volume of the net pen and increasing stocking densities of the fish to potentially stressful levels.

Increased risk of diseases

Contact of the fish with stinger cell bearing biofouling organisms such as hydroids can lead to gill and skin damage[9,10,11,12,13]. Biofouling can also act as an infection reservoir and vector for various fish pathogens, leading to diseases such as vibriosis[14], amoebic gill disease[15] or parasitic blood flukes[16,17].

Reduced effectiveness of salmon lice 'cleaner fish'

Norwegian and Scottish salmon farms use 'cleaner fish' such as lumpsucker and wrasse species as a natural remedy to reduce the presence of salmon lice, which they pick off the cultured fish. However, given the opportunity, the 'cleaner fish' preferentially feed on biofouling organisms on the cage nets instead of on the salmon lice, and as a result, their de-lousing performance drops, leading to an increased prevalence of salmon lice[18,19,20].

Why are salmon lice a problem?

Salmon lice live and multiply on salmon and trout in salt water. In the event of a heavy infestation, the lice can inflict wounds on the fish that can cause infections and problems with the salt balance[21]. If uncontrolled, salmon lice impair the health and welfare of the fish.

Salmon lice live and reproduce on salmon and trout in seawater.
Photo: Pål Mugaas Jensen

TACKLING BIOFOULING IN AQUACULTURE

In essence, there are two approaches to address biofouling of nets used in mariculture of finfish, namely (i) preventive biofouling management using antifouling coatings and (ii) reactive biofouling management, mainly in situ net cleaning and to a lesser extent regular exchange of nets.

Preventive biofouling management

A common method in salmon farming in Norway, Scotland and Chile, as well as in mariculture of seabass and seabream in the Mediterranean, is to impregnate aquaculture nets with a biocidal antifouling product which prevents or minimises attachment and growth of fouling organisms. Nets are treated in either a dipping tank or a vacuum impregnator.

The Aquaculture Stewardship Council (ASC) Salmon Standard prescribes that biocidal antifouling net coatings shall only contain biocide(s) that are approved according to the relevant legislation in the European Union, or the United States, or Australia as these jurisdictions are viewed to be undertaking rigorous assessments of biocides[22].

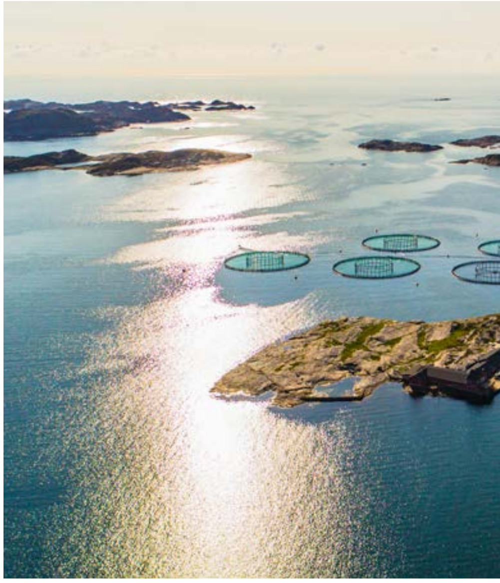
Another way of preventive biofouling management is conducting regular pro-active cleaning or 'grooming' of net pens whereby micro-fouling is removed using a gentle cleaning technique before any macro-fouling gets a chance to settle on nets.

Reactive biofouling management

Removal of biofouling from net pens is mostly done in situ, using water expelled from rotating discs with nozzles mounted onto a 'cleaning rig' that moves along the inside of pens. Water jetting can be high-pressure (pressure at nozzle above 90 bar) or low-pressure (nozzle pressure below 90 bar, usually with large quantities of water). Other, more recently developed net cleaning technologies include brush- or cavitation-based systems. Net cleaning is conducted every few weeks or more frequently, depending on biofouling pressure.

The top metres of a net can be lifted above water and attached to the railing for several days, causing the fouling organisms to dry out, die and eventually fall off.

Another way of reactive biofouling management is a regular exchange of nets during each production cycle.



Disadvantages of reactive biofouling measures

- Net cleaning is labour-intensive, consumes a lot of energy and is costly.
- In situ net cleaning has a **negative impact on fish health and welfare** in several ways. The release of significant amounts of biofouling as cleaning waste can lead to the transmission of fish pathogens[23,9,24,10] as well as gill and skin damage to the fish[11,12,13]. Stress induced by net cleaning may trigger disease outbreaks and increased fish mortality rates.
- Net cleaning has been associated with a loss of appetite in fish and **lower feed ratio** and biomass growth rates.
- In situ net cleaning without waste capture causes organic deposition and **environmental pollution below fish farms**.
- High-pressure water jetting of nets may also release large amounts of **microplastics**.
- Hydroids have a root-like network which is anchored in net filaments and not removed by in situ cleaning, which means that a **newly cleaned net can be re-colonised quickly**. Through release of viable fragments and juveniles which can get carried by currents, **other net pens in a wider area can be affected** by hydroids and other biofouling.
- Net cleaning can also have a negative impact on the wider ecosystem through a **spread of non-indigenous species**[25,26]. Incorrect cleaning practices, which can result in damage to nets[27,28], or a regular exchange of nets during each production cycle, both contribute to the **risk of fish escapes**[29,30,31], which in turn poses an ecological risk to wild fish populations.

Pressure washing of antifouling-treated nets is unsustainable

Most antifouling net impregnations, irrespective of which active substances they contain, are relatively soft and thus a significant portion of the impregnation – and the biocide(s) incorporated therein – may be removed from the net during in situ cleaning using high-pressure water jetting. Any **dislodged coating flakes** will be deposited below the fish farm, leading to **environmental pollution**. This is equally the case for non-degradable inorganic copper-based biocides, or fast degrading organic biocides such as ECONEA® (tralopyril).

Pressure-washing of antifouling-treated nets is clearly an improper, unsustainable and irresponsible use of biocidal antifouling net impregnation products and is therefore prohibited in certain countries such as Chile. The Aquaculture Stewardship Council (ASC) Salmon Standard prohibits high-pressure in situ cleaning of nets impregnated with copper-based products[22].

Alternatively, more gentle non-abrasive cleaning systems based on low-pressure/high water volume or cavitation could be used in combination with antifouling-treated nets, provided it has been demonstrated that the cleaning technique does not damage the coating.

Another approach is to use antifouling coatings that are effective over an entire production cycle or at least a significant portion thereof, and do not require cleaning, whether or not in combination with a limited number of scheduled net exchanges.

NEXT-GENERATION ANTIFOULING

Until a few years ago, most antifouling impregnation products were based on dicopper oxide (Cu_2O) as the active ingredient, sometimes in combination with copper pyrithione. Such copper-only products were usually unable to control hydroids, sea squirts and other copper-tolerant fouling species on net cages and offered only limited protection.

In 2017, the first antifouling net coatings based on ECONEA® as active ingredient were introduced in Norway and a few years later in Chile. Impregnations with ECONEA® have proven much more effective than copper-only products and provide adequate antifouling protection of nets for longer periods of up to 12 months and beyond. Due to their cost-effectiveness, ECONEA®-based products have become the dominant antifouling net impregnation technology in Norway in just a few years.

Net panels with and without antifouling impregnation.
Photo: Steen-Hansen AS

NATURE-INSPIRED ANTIFOULING TECHNOLOGY

ECONEA® (tralopyril) is an arylpyrrole compound whose chemical structure and mode of action (i.e. uncoupling of mitochondrial oxidative phosphorylation) are related to those of pyrrolomycins, natural compounds produced by actinomycetes of the genus Streptomyces. Tralopyril is a synthetic pyrrole compound which demonstrates the best combination of high antifouling performance and durability, low bio-accumulation potential and rapid degradation and de-toxification in the marine environment.

ANTIFOULING PRODUCTS ARE WELL-CHARACTERISED AND UNDERSTOOD

European Biocidal Products Regulation and other legislation

Within the European Economic Area (EEA), which includes Norway, antifouling net impregnation products are regulated under the European Biocidal Products Regulation (BPR, Regulation (EU) 528/2012). In practice, this means that any antifouling impregnation product requires an authorisation before it can be placed on the market, and the active substance(s) it contains must be previously approved for antifouling use. The approval of active substances takes place at Union level and the subsequent authorisation of antifouling impregnation products at Member State level.

ECONEA® (tralopyril) has been approved by the European Commission under the EU BPR as an active substance for use in antifouling products (product type 21) since 2015[32]

ECONEA® is also approved by the US Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as an antifouling agent since 2007[33].

Both the European Union and the United States are considered jurisdictions where rigorous biocide assessments take place, to ensure a high level of protection for humans and the environment. To obtain approval of ECONEA® by the European Commission and the US EPA, Janssen PMP had to generate a very comprehensive data package, **around 150 (!) studies in total**, including physicochemical, physical hazard, analytical, toxicological, environmental fate and ecotoxicological studies, most of which were conducted according to the OECD principles of Good Laboratory Practice (GLP) by independent, accredited laboratories.

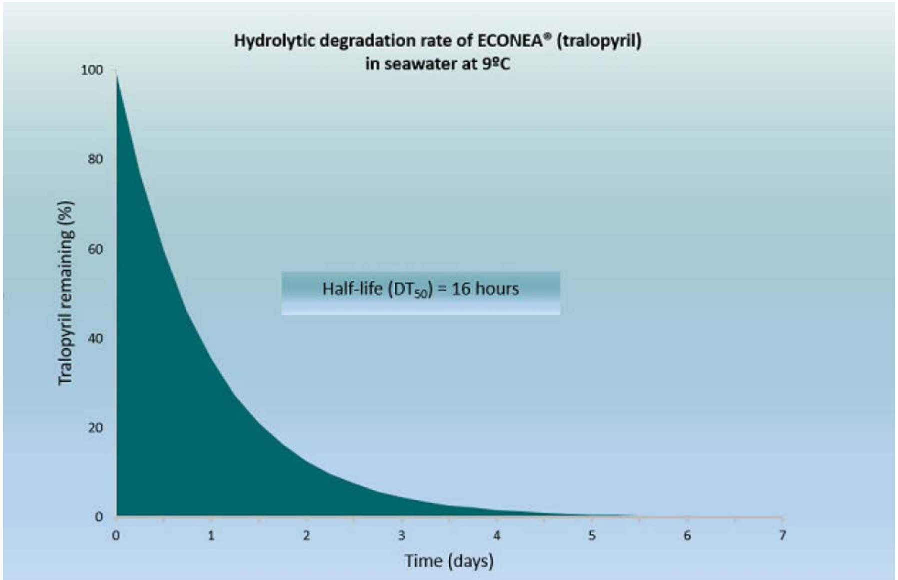
All individual studies were **reviewed and scrutinised by the US EPA and, in the EU/EEA, by experts of all Member States**. Whilst the full study reports themselves are proprietary to Janssen PMP and are therefore not published, **detailed summaries of all studies were made publicly available** for consultation on the website of the European Chemicals Agency (ECHA) following approval of ECONEA® (tralopyril) as an antifouling active substance in 2015[34].

In addition to the approvals of ECONEA® (tralopyril) as an active substance, a first family has been authorised in Norway under the EU BPR, following a rigorous evaluation by the Norwegian Environment Agency (Miljødirektoratet). This evaluation focused on the use of ECONEA® and impregnation products based thereon in Norwegian salmon farms and lead to the conclusion that the impregnation products containing ECONEA® can be used safely from a human health, environmental and dietary perspective. The respective EU BPR Product Assessment Report (PAR) which summarises the conclusions from the successful evaluation is publicly available[35].

Fate and effects of ECONEA® in the environment

In order to prevent attachment and growth of fouling organisms on aquaculture nets, it is necessary for the antifouling active substance to be released in small amounts from the net impregnation product, by controlled leaching. One of the unique properties of ECONEA® (tralopyril) is that it **degrades and detoxifies very rapidly in the marine environment once it has been released**. The pathway and products of this degradation process have been very thoroughly investigated in multiple studies performed with tralopyril and its degradation products. These studies have been evaluated as part of the approval of tralopyril as an active substance for antifouling uses in the EU/EAA under the BPR[32,34], and in the US under FIFRA[33].

The major route by which tralopyril degrades is hydrolysis, the chemical breakdown of a molecule in water. Tralopyril degrades in water very rapidly and this process is even faster in marine water than fresh water. Speed of degradation of a chemical substance is usually expressed as a degradation half-life, i.e. the time taken for the compound to be reduced by half through degradation. The definitive study of hydrolysis half-life, performed according to GLP at different pH levels and temperatures[36], demonstrates that **tralopyril has a half-life by hydrolysis in the marine environment of only 16 hours at 9°C which is a representative temperature for Norwegian waters**. Such studies on hydrolysis are performed in the dark, so clearly demonstrate that the **main degradation pathway of tralopyril is independent of exposure to sunlight**, i.e. it is equally important in the depths of the ocean as in the surface waters.

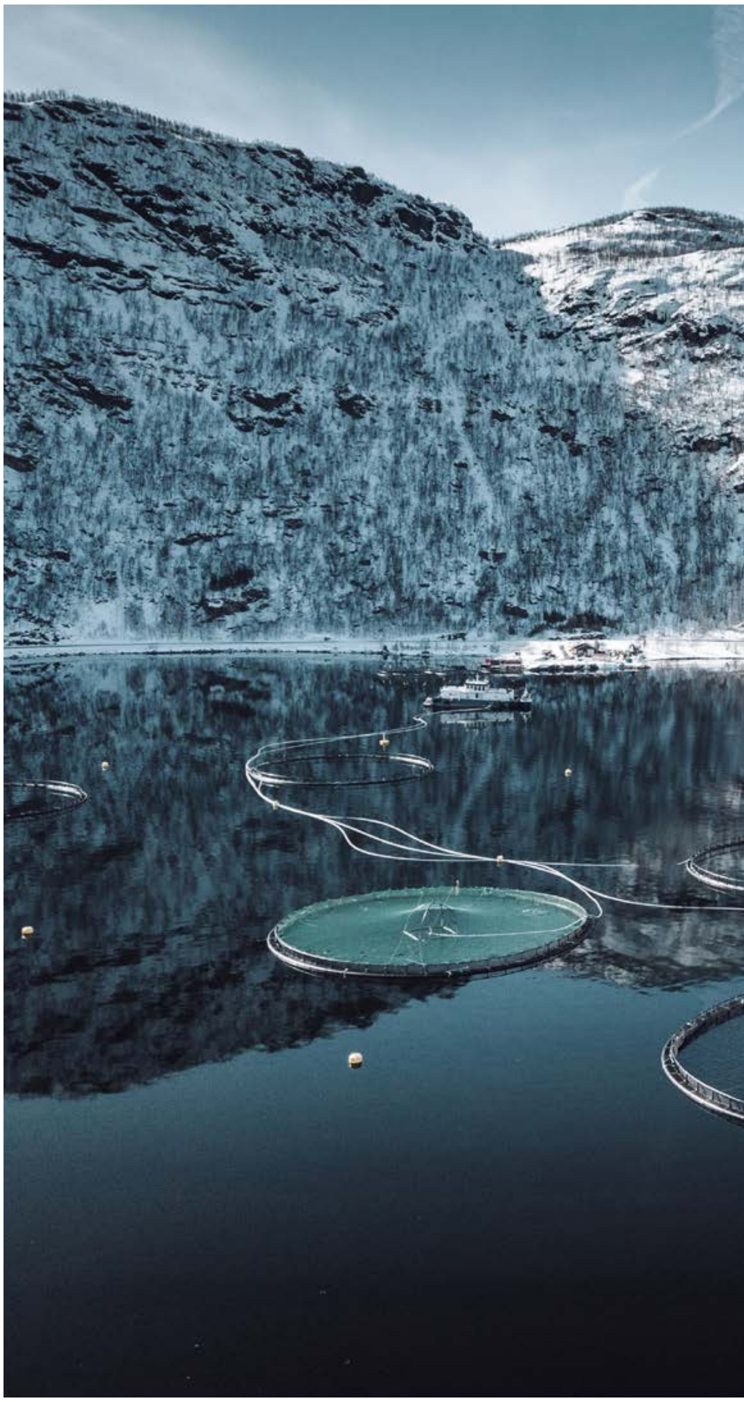


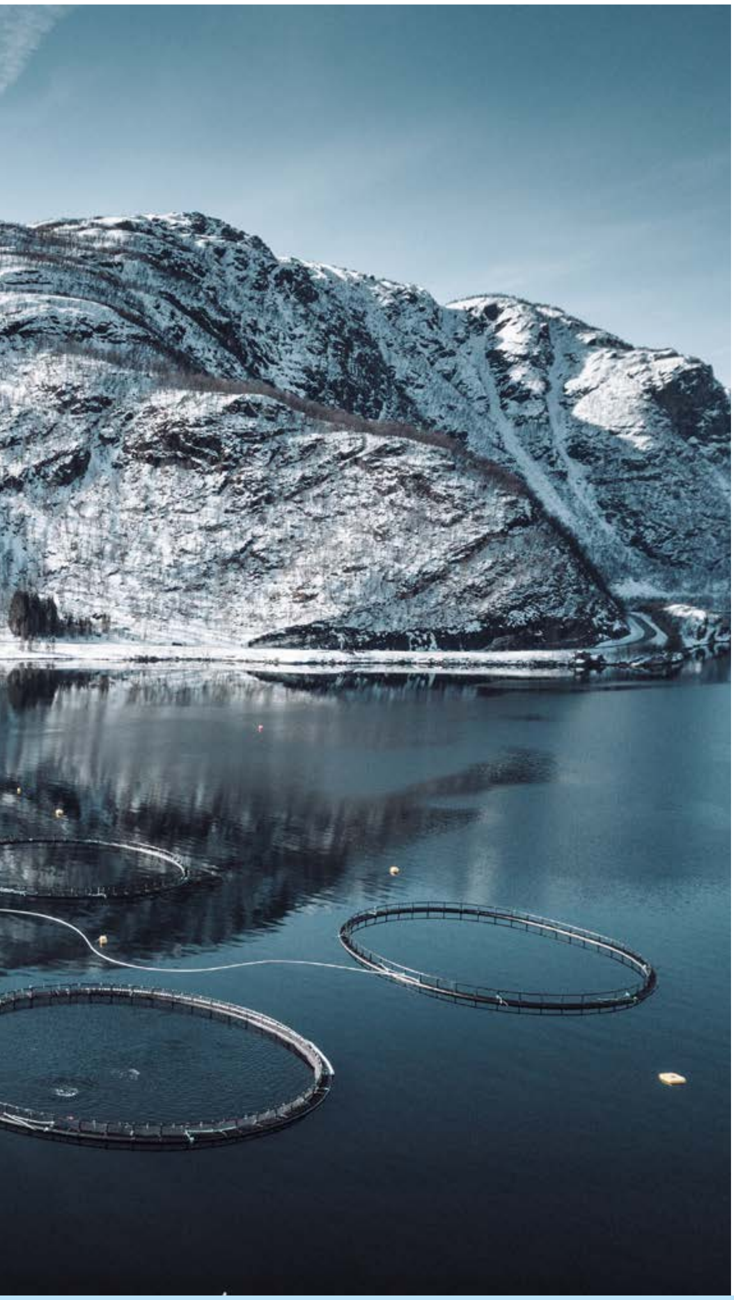
Once released from a net impregnation, ECONEA® breaks down rapidly in seawater

As tralopyril degrades, its molecular composition alters and its toxicity to marine life reduces significantly. The first degradation product of tralopyril (designated CL322,250) is less toxic to aquatic organisms compared to tralopyril itself by a factor of around 200, and this compound also transforms by hydrolysis to another degradation product (designated CL322,248) which is a factor of 600 - 1,200 less toxic than tralopyril. A further, minor, degradation product (designated CL325,195) has a similarly low toxicity. The aquatic toxicity data upon which these factors are based comprises multiple studies (more than 50 individual studies performed with tralopyril and its degradation products), with a range of aquatic organisms including fish, invertebrates, and algae[34], and performed according to GLP in accordance with regulatory guideline protocols.

Degradation by hydrolysis is also augmented in the shallower depths, where sunlight can penetrate, by **photolytic degradation**. From the definitive photolytic degradation study[37], performed according to GLP, the half-life of tralopyril is estimated to be 5.1 – 8.9 hours, after any contribution by hydrolysis is corrected for. The major degradation products of photolysis are the same as those of hydrolysis, so have the same ecotoxicity profile. Several additional, minor degradation products resulting from photolysis are also assessed to have significantly lower toxicity to aquatic life then tralopyril itself.

Finally, **biological degradation** caused by microorganisms is another relevant degradation process for tralopyril, since it is an organic molecule. In a guideline, GLP study[38], tralopyril does not meet the criteria to be considered ‘readily biodegradable’, i.e. it is not rapidly degraded by microorganisms. However, further studies performed in simulated water/sediment systems, under both aerobic[39] and anaerobic[40] conditions demonstrate that tralopyril is biodegraded in seawater and freshwater systems, in the water column and in the sediment compartment of each, and in the presence and absence of oxygen. These studies were also conducted in test vessels protected from direct sunlight, confirming that the biological processes of degradation can occur at depth as well as in more shallow waters.



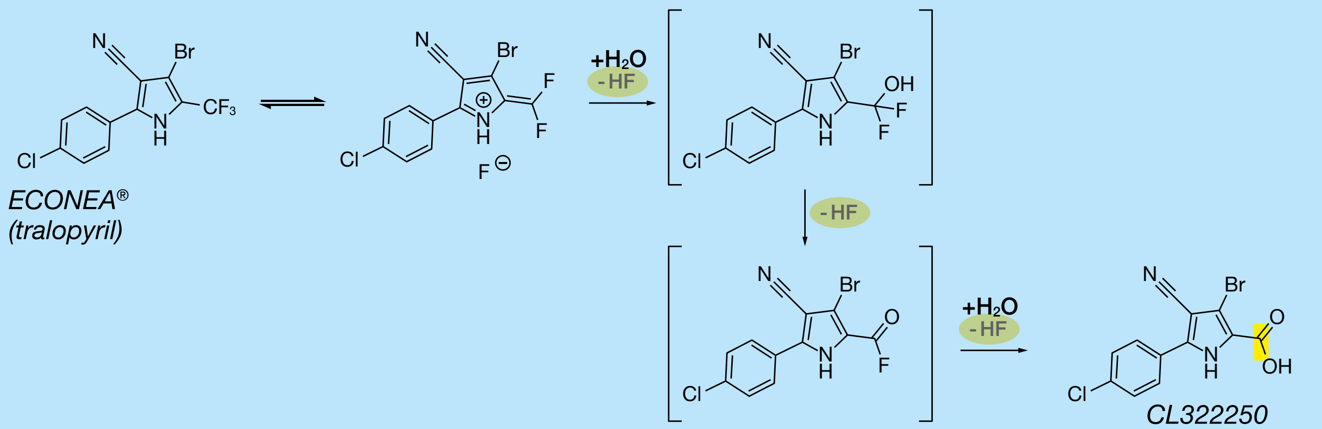


PFAS considerations

Per- and Polyfluoroalkyl Substances (PFAS) are the subject of a recent proposal for restriction under the EU REACH legislation[41], which proposes to restrict or ban all PFAS substances that meet the very broad OECD definition of PFAS. If this proposal would come through, this would mean that over 10,000 substances would be restricted or banned in the EU/EEA. The restriction is proposed due to concerns of health and environmental effects but, in particular, the assertion that all PFAS substances and/or their degradation products are highly persistent in the environment. ECONEA® (tralopyril) is one substance that meets the very broad OECD definition of PFAS due to the presence of a single trifluoromethyl (CF3) group in the molecule.

The EU REACH restriction proposal has been the subject of a public consultation, to which more than 5,600 comments have been submitted. One of the proposal options is for a time-unlimited derogation for biocidal active substances such as tralopyril, where the evaluation of such substances, including environmental persistence, is already addressed under the EU BPR. This would mean that tralopyril would not be subject to the EU REACH restriction proposal but would continue to be evaluated under the EU BPR.

As explained in the previous section, **tralopyril is <u>not</u> a persistent substance** and degrades very rapidly in the marine environment to substances which are significantly less ecotoxic than tralopyril itself. Critically, in the context of PFAS, the breakdown pathway of tralopyril in the aquatic environment is well characterised through environmental fate studies performed by independent laboratories under Good Laboratory Practice (GLP). As tralopyril degrades, the trifluoromethyl (CF3) group is transformed into a carboxylic acid (COOH) group. In this process, **PFAS components such as trifluoroacetic acid (TFA) are <u>not</u> and <u>cannot</u> be formed**.



The degradation pathway of ECONEA® (tralopyril) is well-characterised and understood:

- Upon hydrolysis of tralopyril, three equivalents of hydrogen fluoride (HF) are formed and released.
- **The PFAS substance Trifluoroacetic Acid (TFA; CF_3COOH; CAS nr 76-05-1) is not and cannot be formed as the carbon contained in the trifluoromethyl (CF3) group remains attached** due to the stabilizing aromatic effect of the rest of the tralopyril molecule.
- Fluoride ions (F-) are naturally present in seawater, but also in food, drinks, toothpaste, etc.

More recent environmental fate studies on tralopyril, in which specific and very sensitive analytical methods for the detection of TFA and HF have been used, confirm the complete absence of TFA in seawater, as well as a proportionate and expected increase in F- ion levels as tralopyril degrades to the hydrolytic metabolite CL322,250.

Remarks:

Since seawater contains about 200 ng TFA per litre[42,43,44,45], the presence of TFA in fish farms should not necessarily be associated with the use of ECONEA-based impregnation products. Unfortunately, TFA is ubiquitous in the environment and can come from numerous sources.

Germany's Environment Agency (UBA) has set a human health "orientation value" limit of 60 µg/l for TFA in drinking water and a "precautionary measure" of 10 µg/l[46].

Steen-Hansen

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Bioaccumulation study with fish

The use of ECONEA® (tralopyril) on nets used in aquaculture means that we should be justifiably concerned about any residues that could be present in farmed salmon or other fish that we find on our dinner plate. A key study in the dossiers submitted for the EU BPR and US EPA (FIFRA) approvals addresses this.

A bioconcentration study, with carp[47], was performed according to OECD guidelines and GLP principles. Such a study is designed to determine the bioaccumulation potential of a substance, i.e. how much of the substance is found in the fish tissue after a period of exposure to the substance in water, relative to the concentration of substance in the water.

A substance is considered to be bioaccumulative under the EU REACH Regulation[41] if its bioconcentration factor (BCF) is equal to or greater than 2000 l/kg, and very bioaccumulative if its BCF is equal to or greater than 5000 l/kg. In the bioconcentration study with fish, although the concentration of tralopyril in water was maintained at a constant level throughout the 28-day exposure period, no tralopyril was detected in any fish tissue sample taken at any timepoint during the exposure. All analytical measurements of tralopyril in the fish tissue were below the analytical detection limit of 0.15 ng/g, leading to a calculated BCF value of less than 3.2 l/kg.

The bioconcentration study clearly demonstrates that **tralopyril has no potential for bioaccumulation in fish**, and this has been borne out by extensive residue analysis of salmon samples collected at Norwegian salmon farms using ECONEA® (tralopyril) containing net impregnation products (see below).

Monitoring studies in Norwegian fish farms

Monitoring of tralopyril levels in both seawater and fish tissue has been carried out over an extended period at Norwegian salmon farms where ECONEA® (tralopyril)-based net impregnation products have been in use.

At each of the fish farms, the majority of nets used during a full production cycle were treated with tralopyril-based impregnation products. These included the smolt nets, and ongrowing nets with which these were replaced later in the cycle.

A) Collection and analysis of seawater samples

Seawater samples were taken at minimum five sampling locations, from 2 metres distance from the treated nets to around 1000 metres distance in the direction of the prevailing current, and at depths of 1 metre to over 300 metres, representing the area in which tralopyril released from the coatings could theoretically be found. Samples of seawater were taken at timepoints of approximately 3 months and 5 months post first deployment of the treated nets, and analysis was performed under GLP for the presence of tralopyril and its major degradation products[48,49,50,51].

Around 200 samples of seawater were taken and analysed in all. In over 90% of the seawater samples, tralopyril was undetected (i.e., below the analytical detection limit of 2 ng/L); in the remainder, the levels were generally in the range 2 – 5 ng/L, with the overall average for the full dataset of 1.2 ng/L. A similar picture was seen for the degradation products, with the majority of seawater samples analysed showing undetectable levels.

Thus, it is observed that the use of nets treated with ECONEA® (tralopyril) based impregnation products **does not lead to any significant levels of tralopyril or any of its metabolites being detected in the water column**, and that there is no associated risk to aquatic organisms.

Niskin water sample bottle. Photo: Akvaplan-niva

Extensive monitoring has shown that ECONEA® is undetected in any fish tissue samples analysed to date

B) Collection and analysis of fish samples

Whole Atlantic Salmon were collected from each of the cages treated with tralopyril-based net impregnation products at three timepoints during the production cycle – at approximately 3 months and 5 months after their first introduction to the marine environment, and just before harvest which was after 15 – 17 months at sea, and 4 – 5 kg weight. More than 80 whole fish samples were collected and analysed.

Analysis of a typical fillet (including skin) from each fish was analysed for the presence of tralopyril and its major degradation products, under GLP[43,44,45,46,52,53]. Tralopyril and both degradation products were undetected (i.e., below the analytical detection limits of 1 µg/kg for tralopyril and 5 µg/kg for the degradation products).

The results of these fish residue analyses clearly demonstrate that **neither tralopyril nor its degradation products accumulate in salmon tissue**, and fully corroborate the fish bioconcentration study described above. It is also clear that salmon grown in cages treated with ECONEA® (tralopyril)-based net impregnation products pose **no dietary risk** to the consumer.

Human health considerations

Tralopyril, in common with all biocidal active substances, is inherently toxic to humans. Tralopyril and net impregnation products based thereon must therefore be used in a responsible manner. In an industrial setting, exposure by ingestion is unlikely, but possible dermal and inhalation exposure needs to be considered.

As part of the approval process for antifouling net impregnation products under the EU BPR, risk assessments for tasks involving the handling of impregnations containing tralopyril must be conducted, where the predicted exposure to the active substance in a worst-case industrial setting is compared to an Acceptable Exposure Level (AEL) derived from the toxicity data for that substance. The AELs for the different exposure routes are derived as part of the approval process for each active substance and are agreed by the EU Member States as the threshold levels that must be used in risk assessments under the EU BPR.

A comparison of the medium-term AELs derived for tralopyril and cuprous oxide (copper(I) oxide, CAS no. 1317-39-1) is shown in **Table 4**. This comparison clearly shows that the **acceptable level of exposure to tralopyril is broadly similar to that of cuprous oxide**. It is also important to take into account that tralopyril is generally present in net impregnation products at significantly lower concentrations than cuprous oxide, which results in a **lower exposure to tralopyril compared to cuprous oxide**.

Table 4 Medium-term Acceptable Exposure Levels for ECONEA® (tralopyril) and cuprous oxide

Medium-term AEL, in mg/kg/day	ECONEA® (tralopyril)	Cuprous oxide
Inhalation route of exposure	0,058	0,082
Dermal route of exposure	0,060	0,082

A first family of antifouling net impregnation products containing tralopyril which has been approved under the EU BPR has been assessed as above and found to be safe, subject to certain safety precautions. The risk to health of workers using net impregnation products containing tralopyril is mitigated by the use of appropriate engineering controls, ventilation, and Personal Protective Equipment (PPE). A worker applying a net impregnation containing tralopyril or deploying a net treated with an impregnation containing tralopyril at an aquaculture facility would typically need to wear gloves and a coated overall to ensure a safe use.

NEED FOR A HOLISTIC APPROACH

Biofouling control technologies are crucial and indispensable to the aquaculture industry to ensure fish welfare in a clean and healthy environment, and minimise fish mortality rates during the grow-out phase at sea.

Antifouling net impregnations products, due to their nature, carry an intrinsic risk and therefore need to be regulated and used responsibly. A zero-risk approach, which would require the removal of effective antifouling net impregnations from the market, would lead to inferior control of fouling on aquaculture nets and regrettable compromises regarding the health and welfare of the farmed fish.

The better approach with regard to net impregnations from a societal point of view is to adopt a holistic approach, whereby risks and benefits are carefully balanced.

From that perspective, effective antifouling net impregnations based on a well-understood and well-documented, fast-degrading biocide such as ECONEA®, showing leaching rates within environmentally acceptable limits, that have been risk-assessed by regulatory authorities according to prescribed procedures and government regulations, are a valuable and proven biofouling management strategy in mariculture of finfish, to support fish health and welfare while minimising impacts on the environment.

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