



### FOI on Imidacloprid (BMK08/Ectosan/D10 Aquatic Blast)

To:

Norwegian Ministry of Trade, Industry & Fisheries: [postmottak@nfd.dep.no](mailto:postmottak@nfd.dep.no)

Norwegian Food Safety Authority: [innsynshenvendelser@mattilsynet.no](mailto:innsynshenvendelser@mattilsynet.no)

Norwegian Ministry of Climate & Environment: [postmottak@kld.dep.no](mailto:postmottak@kld.dep.no)

Date: 17 March 2020

From: Scottish Salmon Watch

Please provide information on Imidacloprid (BMK08/Ectosan/D10 Aquatic Blast) including discharges and disposals via Benchmark's 'CleanTreat' and Salmo Pharma.

Fish Farmer magazine [reported in February 2020](#) that "over the last 24 months, more than 35,000 tonnes of salmon in five Norwegian farms have been treated with BMK08":

**Fish Farmer**

## Sea Lice CleanTreat

Norwegian scale up for award winning UK innovation

11 Feb 2020

THE company behind the prize winning CleanTreat filtration technology that cleanses treatment water after delousing is looking to scale up the system. Benchmark Holdings said last month it plans to invest £19 million in the breakthrough innovation ahead of the launch of its new sea lice medicine, BMK8 (formerly known as Ectosan), due in the first half of 2021.

Over the past 24 months, more than 35,000 tonnes of salmon in

five Norwegian farms have been treated with BMK08, achieving approximately 99 per cent efficacy, said Benchmark.

The compound must be used in conjunction with CleanTreat, which removes medicinal residues from treatment water.

Benchmark said there is growing interest from customers for the product and it estimates that BMK08/CleanTreat sales could reach £50 million in Norway

The article also reported:

Norwegian agencies have been strongly supportive of the system's development and it will be the first market for a commercial roll-out.

Please name the salmon farms including site name and company responsible for the operation.

Please provide details on the use, discharge and/or disposal of the Imidacloprid (BMK08).

No information on Imidacloprid is [reported publicly via the annual chemical use data published by FHI in February 2020 including 2019 data](#):



[Forside](#) > [Helse i Norge](#) > [Legemiddelbruk](#) > 2019: Bruk av legemidler i fiskeoppdrett

ARTIKKEL

Legemidler i fiskeoppdrett

# 2019: Bruk av legemidler i fiskeoppdrett

Publisert 27.02.2020

Artikkelen viser forbruket av legemidler i norsk fiskeoppdrett i perioden 2010–2019. Tallene er basert på innrapportert salg til Folkehelseinstituttet fra legemiddelgrossister og förfirmaer.

**Tabell 2. Midler mot lakselus (kg aktiv substans)**

	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
azametifos	3346	2437	4059	3037	4630	3904	1269	204	160	154
cypermetrin	107	48	232	211	162	85	48	8	0	0
deltametrin	61	54	121	136	158	115	43	14	10	10
diflubenzuron	1839	704	1611	3264	5016	5896	4824	1803	622 <sup>1</sup>	1296
emamektin	22	105	36	51	172	259	232	128	87	114
teflubenzuron	1080	26	751	1704	2 674	2509	4 209	293	144	183
hydrogen- peroksid (100%) (tonn)	3071	3144	2538	8262	31577	43246	26597	9277	6735	4523

Where is the data for Imidacloprid? If five salmon farms and over 35,000 tonnes of salmon in Norway have been treated over the last two years then surely data should be reported for 2018 and 2019?

Norwegian Fish Farmer magazine [reported in June 2016](#) that [Novartis had obtained a US patent for Clothianidin in 2014](#) and [cited the 2015 US patent on Imidacloprid for use in salmon farming](#).

### Patentert metode

To av dem som står bak AVSI, som er den kanadiske samarbeidspartneren i prosjektet, John O'Halloran og John Terence Drost, har nemlig [patentert en fremgangsmåte for å belegge fiskefôr](#) med en «bærer» som skal sørge for at legemidler i neonicotinoid-klassen i langt større grad blir spist og tatt opp av fisken når de gis i fôret.

I patentet viser de til et forsøk Novartis har beskrevet i deres patentsøknad for [et neonicotinoid-middel som heter «clothianidin»](#).

Der konkluderer Novartis med at det kun er clothianidin av neonicotinoidene de testet som gir full effekt. Og at for eksempel at et annet velkjent middel, imidacloprid, dermed ikke er egnet som fôrbasert lakselusmiddel. [Se tabellen her](#)

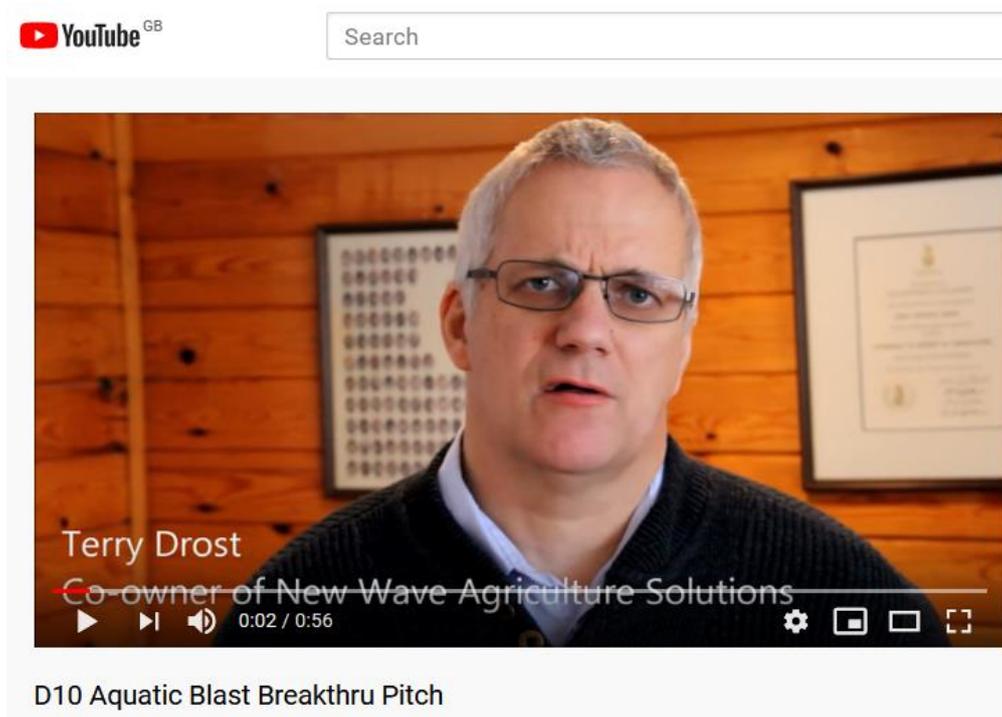
I patentet til O'Halloran og Drost hevder de derimot at de har funnet en bærersubstans som også gjør de andre stoffene egnet. Derfor krever de i patentet at denne metoden skal gjelde stoffer som imidacloprid, acetamiprid, dinotefuran, nitenpyram, thiacloprid, thiamethoxam.

Selv om patentet ramser opp en rekke neonicotinoider, er det varianten «**imidacloprid**» som vies mest fokus i patentet. Kyst.no spør Rikhardsen om det er dette konkrete virkestoffet det jobbes med?

**- Jeg kan bare bekrefte at det i patentet er beskrevet en rekke varianter, men jeg kan verken bekrefte eller avkrefte at det er akkurat imidacloprid, sier han.**

The article ended by directing readers to a [You Tube presentation dated December 2014 by Terry Drost of New Wave Agriculture Solutions](#) which included:

"We have developed a new treatment for sea lice called D10 Aquatic Blast. D10 Aquatic Blast is based on a compound used in agriculture for the last 20 years. We are using it in salmon feeds in the marine environments for the first time in the world. We would like to talk to you about how we can get D10 Aquatic Blast approved for use in Canada and the rest of the world."



Fiskeribladet/Tekfisk [reported in June 2018](#):

FISKERI | HAVBRUK | TEKNOLOGI | FOU | MENINGER

Tekfisk

## Har fått forskningstillatelse for å teste ut nytt lusemiddel

Salmo Pharma har fått innvilget forskningstillatelse i Nordland.



Vegard Solsletten

6. juni 2018 08:16

Selskapet har fått tillatelse til å benytte lokaliteten Nord Gåsvær i Herøy kommune. Lokaliteten disponeres også av Seløy Sjøprodukter, Seløy Sjøfarm, Bindalslaks og Sinkaberg-Hansen.

Tillatelsen til Salmo Pharma er gitt for 780 tonn MTB og er tidsbegrenset frem til 12. desember 2022.

Forskingstillatelsen skal brukes til klinisk utprøving av lusemiddelet D-10 Aquatic Blast for å dokumentere effekt på lakselus, sikkerhet ved medisinføring, og påvirkning på miljø.

IntraFish har tidligere omtalt at canadiske Aquaculture Veterinary Services International (AVSI) sammen med Salmo Pharma har utviklet det nye veterinære legemiddelet D-10 Aquatic Blast.

Veterinær Bjørn-Inge Rikhardsen, mannen bak Salmo Pharma, har uttalt til IntraFish at han håper legemiddelet kan bli et veldig viktig bidrag til utfordringene med lakselus.

(VILKÅR)

The article links to another article [published in Intrafish in June 2018](#):



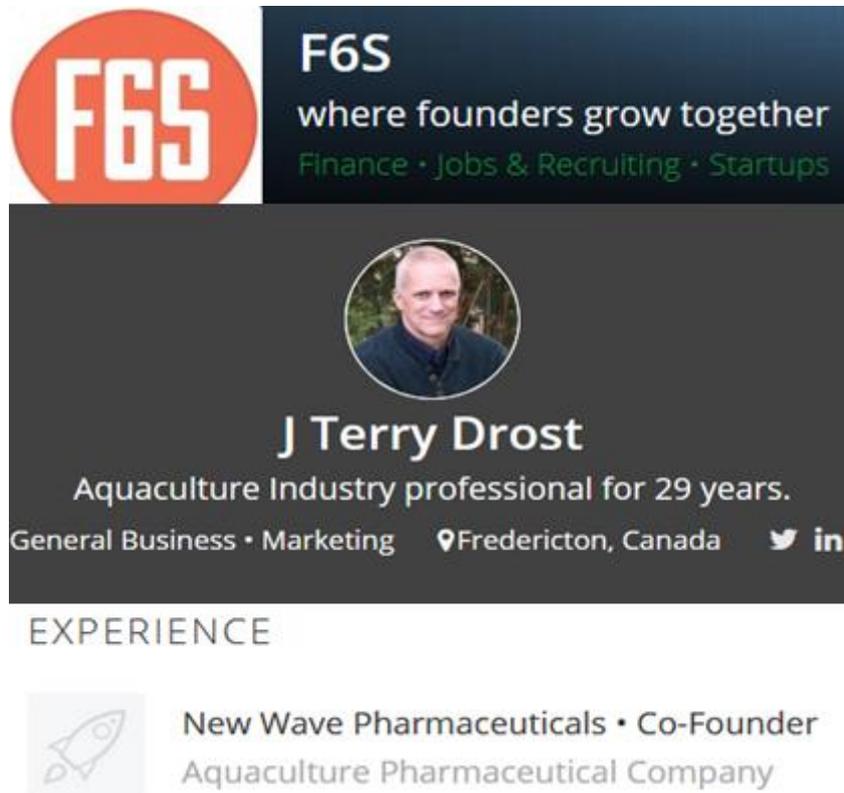
## Søker to FoU-tillatelser for nytt lusemiddel

Det nyetablerte selskapet Salmo Pharma har søkt Fiskeridirektoratet om to FoU-tillatelser for utprøving av et nytt forbedret legemiddel mot lakselus.

28. juni 2018 7:38 CET OPPDATERT 28. juni 2018 7:38 CET  
Av Anders Furuset

Det fremgår av dokumenter IntraFish har fått innsyn i. Deler av dokumentene, som hele søknaden til Statens Legemiddelverk, er imidlertid unntatt innsyn grunnet forretningskritiske

It is difficult to access any information on New Wave Agriculture Solutions but there is an [online listing for J Terry Drost at tech funding start up F6S](#):



**F6S**  
where founders grow together  
Finance • Jobs & Recruiting • Startups

  
**J Terry Drost**  
Aquaculture Industry professional for 29 years.  
General Business • Marketing • Fredericton, Canada

EXPERIENCE

 New Wave Pharmaceuticals • Co-Founder  
Aquaculture Pharmaceutical Company

Terry Drost, Vice-President/COO New Wave Pharmaceuticals Inc (based in New Brunswick in Canada), [told Salmon Business in August 2018](#):



"Once a sea lice outbreak hits them, they are faced with the choice of doing nothing and allowing up to 100% of their fish to be eaten alive by sea lice or applying mechanical treatments that can result in large amounts of fish damaged or killed..... we need to be allowed the emergency use of innovative, safe and efficacious new treatments to control sea lice."

The Fish Site [reported in June 2017](#):

## Patent sought for neonicotinoid-based sea louse treatment

HEALTH NUTRITION



by Rob Fletcher  
2 June 2017, at 12:00am

Details of an application for a patent concerning a neonicotinoid-based in-feed sea louse treatment have been recently published in the US.



The treatment has been developed by two Canada-based scientists – John O’Halloran and John Terence Drost – and is set to be administered orally, via medicated feeds, to salmon ranging from 50 g to 5 kg. Trials conducted by the scientists have shown it to be effective against both *Lepeophtheirus* and *Caligus* lice species, although the principle target is *Lepeophtheirus salmonis*. According to the patent application, salmon can be safely harvested and consumed within 21-25 days after treatment, or when the neonicotinoid residue in the fish is below 0.02 parts per million.

Although the patent is still pending, independent research into the possible efficacy of neonicotinoids against sea lice has also been promising. Indeed, a [paper](#) published in the [Journal of Fish Diseases](#) last year by Aaen and Horsberg, from the [Sea Lice Research Centre](#) at the NMBU School of Veterinary Science, showed the nicotinic (neuronal) acetylcholine receptor (nAChR) to be a suitable target for compounds such as neonicotinoids.

These compounds consist of seven separate insecticides – imidacloprid, thiacloprid, thiamethoxam, acetamiprid, nitenpyram, clothianidin and dinotefuran – and are used to combat pest organisms on a wide range of crops, as well as parasites on animals. In Australia and New Zealand, products containing compounds from this group are available for use on sheep; otherwise, companion animals are the main consumers of these substances.

A prominent feature of neonicotinoids is their specificity to invertebrate nAChR compared to vertebrate nAChR and this group of compounds is reported to induce toxic effects on crustaceans when distributed in extremely low concentrations.

Despite this, neonicotinoids are not without controversy, as their use as pesticides on crops has been linked to a steep decline in bee numbers, while their relatively long persistence in aquatic environments could, the scientists suggest, complicate their use as antiparasitic compounds. Nevertheless their trials showed that imidacloprid – which is the compound included in the current patent application – was highly effective against *L. salmonis*. Exposing lice to imidacloprid for 30 minutes at a concentration of 50 mg L<sup>-1</sup>, or for 24 hours at 5 mg L<sup>-1</sup> generated a high level of immobilization.

Although another neonicotinoid, nitenpyram, did not yield a similar effect, the researchers concluded that the nicotinic acetylcholine receptor was a sensitive target for novel salmon lice medicines.

Further details of the US patent for Imidacloprid are available [online here](#)



US 20170135956A1

(19) **United States**

(12) **Patent Application Publication**  
O'HALLORAN et al.

(10) **Pub. No.:** US 2017/0135956 A1  
(43) **Pub. Date:** May 18, 2017

(54) **FISH FEED COMPOSITIONS CONTAINING A NEONICOTINOID FOR PREVENTING AND TREATING PARASITE INFECTIONS**

(71) Applicants: **John O'HALLORAN**, Old Ridge (CA); **John Terence DROST**, Douglas (CA)

(72) Inventors: **John O'HALLORAN**, Old Ridge (CA); **John Terence DROST**, Douglas (CA)

(21) Appl. No.: **15/321,896**

(22) PCT Filed: **Jun. 24, 2015**

(86) PCT No.: **PCT/IB2015/054749**

§ 371 (c)(1),  
(2) Date: **Dec. 23, 2016**

**Related U.S. Application Data**

(60) Provisional application No. 62/016,389, filed on Jun. 24, 2014.

**Publication Classification**

(51) **Int. Cl.**  
*A61K 9/16* (2006.01)  
*A61K 9/00* (2006.01)  
*A23K 20/10* (2006.01)  
*A23K 20/158* (2006.01)  
*A23K 10/30* (2006.01)  
*A61K 31/4439* (2006.01)  
*A23K 50/80* (2006.01)  
(52) **U.S. Cl.**  
CPC ..... *A61K 9/167* (2013.01); *A61K 31/4439* (2013.01); *A61K 9/1617* (2013.01); *A61K 9/1658* (2013.01); *A61K 9/0053* (2013.01); *A23K 50/80* (2016.05); *A23K 20/158* (2016.05); *A23K 10/30* (2016.05); *A23K 20/10* (2016.05)

(57) **ABSTRACT**

The present disclosure relates to methods of preventing or treating parasite infection in a plurality of fish in need thereof, comprising administering to the fish an effective amount of a medicated fish feed. The medicated fish feed comprises fish feed granules or pellets coated with a composition comprising a neonicotinoid such as imidacloprid and a carrier having a high apparent digestibility coefficient such as a processed/cooked corn protein concentrate.

A PhD thesis - "Chemotherapeutants against salmon lice *Lepeophtheirus salmonis* – screening of efficacy" - [published by the Norwegian University of Life Sciences in 2016](#) identified Imidacloprid as a 'Test Substance':

Table 2. List of substances utilized in the studies, grouped according to the IRAC mode of action classification.

IRAC group	Substance	General mode of action	Mode of action	Substance group	Project candidate
1A	Propoxur	Nervous system	Acetylcholinesterase inhibitor	Organophosphates	Test substance
1B	Azamethiphos	Nervous system	Acetylcholinesterase inhibitor	Organophosphates	Model substance
2B	Pyriprole	Nervous system	GABA-gated chloride channel blocker	Phenylpyrazoles	Test substance
3	Cypermethrin	Nervous system	Sodium channel modulator	Pyrethroids	Model substance
4A	Imidacloprid	Nervous system	Nicotinic acetylcholine	Neonicotinoids	Test substance

Table 6: Concentrations immobilizing 50 (EC<sub>50</sub>) and 90 (EC<sub>90</sub>) % of preadult *L. salmonis* parasites exposed to neonicotinoids for 24 hours. The 90 % confidence intervals are provided in brackets when applicable.

Substance	EC <sub>50</sub> (µg/L)	EC <sub>90</sub> (µg/L)
Imidacloprid	97.6 (74.2-148.6)	334.2 (152.3-733.75)

North America Aquaculture [reported in April 2018](#):

## Aquaculture North America

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### Pesticide banned in oyster farming

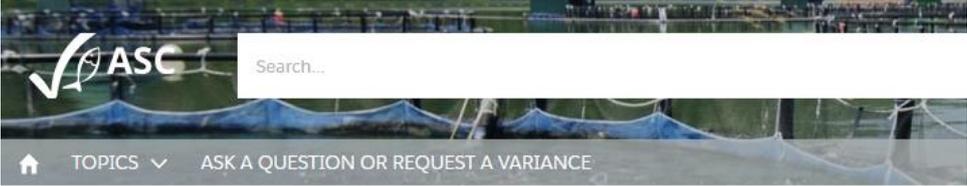
The Washington Department of Ecology has banned a pesticide that was approved two years ago for oyster growers to kill burrowing shrimp.

The department said it made the decision after a lengthy evaluation of the environmental impacts of the pesticide, imidacloprid. The pesticide belongs to a class of chemicals called the neonicotinoids, which act on the central nervous system of insects.

The state announced Monday that it is too harmful to the ecosystem and decided to deny a request for its approval.

“The science around imidacloprid is rapidly evolving and we can’t ignore it. New findings make it clear that this pesticide is simply too risky and harmful to be used in Washington’s waters and estuaries,” state Ecology Director Maia Bellon said in a press release.

Scottish Salmon Watch first discovered that Ectosan (which was [launched in 2017](#) and [re-named by Benchmark as BMK08 in 2019](#)) was Imidacloprid last week following a tip-off to view [details on the Aquaculture Stewardship's web-site](#):



ASC Search...

TOPICS ▾ ASK A QUESTION OR REQUEST A VARIANCE

SALMON

**Q&A66\_Salmon\_V1.1\_5.2.5**

🕒 20-May-2019 · Knowledge

<b>TITLE</b> Q&A66_Salmon_V1.1_5.2.5	<b>PUBLICATION STATUS</b> Published
<b>NAME OF CAB</b> <a href="#">Delete</a>	<b>DATE OF SUBMISSION</b> 13/02/2019
<b>PROSPECT / CERTIFICATE HOLDER</b>	<b>ASC DOCUMENT INDICATOR/ CLAUSE</b>
<b>CROSS REFERENCE TO OTHER VR'S / QA'S</b>	<b>ASC DOCUMENT INDICATOR/ CLAUSE 2</b>
<b>DOCUMENT (REFERENCE)</b> Salmon	<b>ASC DOCUMENT INDICATOR/ CLAUSE 3</b>
<b>VERSION</b> 1.1	<b>ASC DOCUMENT INDICATOR/ CLAUSE 4</b>
<b>PRINCIPLE</b>	
<b>CRITERION</b>	
<b>INDICATOR</b>	
<b>SUPPORTING EVIDENCE</b>	
<b>COUNTRY</b>	
<b>REGION</b> ⓘ	
<b>APPROVED REGION</b>	
<b>DATE INTERNAL CHECK STARTED</b>	
<b>DATE INTERNAL CHECK FINISHED</b>	

## BACKGROUND <sup>1</sup>

Interpretation request (PTI for new sea lice medicine that is not released into the environment).

Mowi Norway AS and Benchmark Rationale for PTI calculation – Ectosan (Imidacloprid):

The ASC standard includes a number of indicators aimed at promoting the responsible use of therapeutic treatments. The environmental risks linked with using chemical therapeutants are linked with the release of such chemicals into a wild environment where non-target organisms may be affected. Therefore, the development of new medicinal treatments that avoid the release of active therapeutants into the environment is in alignment with the ASC aim of environmental stewardship.

Ectosan is a new therapeutic treatment against sea lice which fulfills this intention. Ectosan is administered as a bath treatment in wellboats or other closed contained treatment vessels only. This allows for accurate dosing of the medicine, control of water quality parameters, monitoring of fish welfare and the capture and retention of all treatment water. The fish are pumped into the wellboats with the medicine administered after all fish are onboard. Once the exposure period is completed, the fish are pumped out of the wellboat over a dewatering system fitted with a rinse bar to both separate fish from treatment water and ensure no residues of treatment water remain on the exterior of the fish. All water, including all rinse water, is collected and returned to the wells. Once all fish have been discharged over this system the treatment water is then transferred through CleanTreat, Benchmark's novel water purification system, whereby the medicine is removed from the water prior to the water being discharged back to the environment. The purified water is measured continuously using onboard equipment to ensure levels remain below quantifiable limits.

The Parasiticide Treatment Index (requirement 3.1.7) has been developed during the Aquaculture Salmon Dialogues (ASD) with the aim of "The ultimate goal would be that farms could meet the ASC Salmon Standard without using therapeutants or without the risk of those therapeutants negatively impacting the environment." (page 47 of the ASC salmon standard v1.1). As mentioned earlier the use of Ectosan does not lead to any release of chemical therapeutants into the environment. In addition, the toxicity factor of the active ingredient used in Ectosan (Imidacloprid) has already been established as 85 mg/l (LC 50 for Daphnia, Fossen, 2016) which is higher compared with H<sub>2</sub>O<sub>2</sub> (7.7 mg/l, which is given a toxicity factor of 0 in the ASC-PTI calculation). Therefore, the therapeutant factor for Ectosan will be zero and as a result so will the PTI.

DNV GL response to ASC:

DNV GL can not find PTI calculation values for the therapeutant Ectosan (Imidacloprid) in the ASC Salmon Standard v1.1 – April 2017, Appendix VII: Parasiticide Treatment Index and therefore needs clarification and determination from ASC related to which values shall be used when PTI is calculated. The text below is from page 95 in the ASC Salmon Standard v1.1 – April 2017, Appendix VII: Parasiticide Treatment. DNV GL interpretation of this text is that it is ASC and the Technical Advisory Groups responsibility to determine which values shall be used when PTI is calculated for use of therapeutant Ectosan (Imidacloprid). DNV GL can not approve the given values from the user or producer of the therapeutant Ectosan (Imidacloprid) without a clarification and determination with acceptance of the given values from ASC.

(page 95 in the ASC Salmon Standard v1.1 – April 2017)

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## QUESTION

(page 95 in the ASC Salmon Standard v1.1 – April 2017)

Updating PTI with new information:

If new therapeutants become available for sea lice treatment, or if new treatment method are developed, the Technical Advisory Group of the ASC may be asked to determine a therapeutic factor or treatment factor for that new parasiticide or new method, following guidelines for assignment of factors left by the SAD SC.

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## ASC INTERPRETATION

The PTI-index is calculated using the following formula:

$$PTI = [(therapeutant\ factor) * (treatment\ factor) * (resistance\ factor) * (sensitive\ time\ factor)]$$

Within this formula, the therapeutant factor and treatment factor vary per used active ingredient. The resistance factor and sensitive time factor are based on other variables (i.e. number of treatments applied and lobster presence).

For the therapeutant factor, a classification of the parasiticides used at the time of the Aquaculture Dialogues is given in the table on page 93 (v1.1). This table does not include Imidacloprid (Ectosan). For this substance to qualify, the parameters that contribute to the toxicity factor need to be determined.

These are:

1. Treatment mechanism (bath or oral)
2. Toxicity factor (0-2)
3. Daphnia LC50 ( $\mu\text{g/L}$ )
4. Persistence factor (0-3)
5. Dosage factor (0-3)

The final therapeutant factor is calculated as following:

$$\text{Therapeutant factor} = [(Toxicity\ factor) * (Persistence\ factor) * (Dosage\ factor)]$$

1. Treatment mechanism

Ectosan is applied through a bath treatment. It is noted that the treatment is applied within a well boat and treatment water is purified before released back into the environment.

2. Toxicity factor (0-2) and 3. Daphnia LC50 ( $\mu\text{g/L}$ )

The table on page 93 (v1.1) does not reference the sources from which the Daphnia LC50-scores are derived. In order to find consistency in toxicity scoring, the Pesticide Properties Database (PPDB - <https://sitem.herts.ac.uk/aeru/ppdb/index.htm>) was consulted to verify the referenced values in the ASC Standard. The majority of listed LC50-scores were confirmed by this database and as such this database is used as a proxy to derive ecotoxicity values from.

The toxicity factor of the active ingredient used in Ectosan (imidacloprid) has been established as 85 mg/L (Fossen, 2016). This score was confirmed by the PPDB-database (<https://sitem.herts.ac.uk/aeru/iupac/Reports/397.htm>).

As this score is 11 times less toxic as the stated value for H<sub>2</sub>O<sub>2</sub> (7.7 mg/L), a similar rating as H<sub>2</sub>O<sub>2</sub> for toxicity should be given as well (i.e. toxicity factor "0").

4. Persistence factor (0-3)

According to the PPDB-database, imidacloprid has a water-sediment and water phase only DT50-score ("half-life time") of 129 and 30 days, respectively. Compared to the other parasiticides listed in the table on page 93, these values are considered high (i.e. slow breakdown). For this reason a persistence factor of 3 is given.

5. Dosage factor (0-3)

As there is no information available on the dosage applied - a (maximum) score of 3 is given from a precautionary approach.

Summary:

For the application of Ectosan (imidacloprid) via the described process, the following values for the toxicity factor in the overall PTI-calculation need to be used:

$$\text{Therapeutant factor} = [(Toxicity\ factor) * (Persistence\ factor) * (Dosage\ factor)]$$

- Toxicity factor = 0

- Persistence factor = 3

- Dosage factor = 3

$$\text{Therapeutant factor} = [(0) * (3) * (3)] = 0$$

Please note that the use needs to be registered through Appendix VI of the ASC Salmon Standard v1.1.

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## VR/Q STATUS

Closed

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## EFFECTIVE DATE

15/03/2019

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## URL NAME

Q-A66-Salmon-V1-1-5-2-5

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We have released this information today via "[Revealed: Toxic Neonicotinoid Insecticide Used to 'CleanTreat' Lousy Scottish Salmon](#)".

Further information obtained from the Scottish Government - which refers to trials in Norway - was published in December 2019 via [CleanTreat: FOI Disclosures by the Scottish Government to Scottish Salmon Watch](#)

Please consider this a formal request for information via the relevant FOI and Environmental Information regulations.

Please provide the information electronically and/or online.

Please provide a receipt of this FOI request.

Thanks,

Don Staniford

Director, [Scottish Salmon Watch](#)