

Scottish Salmon Watch, 9 July 2021

Strictly Confidential: The Dirty Secrets of Benchmark's 'Novichok for Insects'
(BMK08/Ectosan/Imidacloprid)



- FOI disclosure lifts lid on the banned neonicotinoid Imidicloprid via CleanTreat
- 'Confidential' minutes reveal secret meetings with Scottish Government, SEPA, Veterinary Medicines Directorate & Benchmark to fast-track regulatory approval

- SEPA deliberately concealed 'confidential' information to avoid FOI laws on disclosure
- SEPA knew that Ectosan (BMK08) was Imidacloprid in October 2018 (if not before)

- Fergus Ewing exposed as a bully-boy for the deployment of BMK08/Ectosan in Scotland
- Benchmark issued investment threats if approval of Imidacloprid was not rushed through
 - Field trials of Imidacloprid were permitted in Norway "with a level of discharge that appears to be above the EQS" admitted the Scottish Government in September 2019
 - Benchmark branded as 'arrogant' and 'naïve' by SEPA

- Mowi urged regulators to speed up the slow process for authorization of the bee-killer
 - Scottish Salmon Producers Organisation lobbied SEPA in May 2019 to support Imidacloprid use "which the developers believe has no environmental impact at sea"

- SEPA discussed the use of Imidacloprid with Canada and Norway in the context of OSPAR regulations and the London Convention
- NDA (Non-Disclosure Agreement) signed with Benchmark to avoid public disclosure

Following a [ruling by the Scottish Information Commissioner in April 2021](#), the Scottish Environment Protection Agency (SEPA) finally disclosed some 'commercially confidential' information on Benchmark's CleanTreat and the [toxic neonicotinoid Imidacloprid](#) (marketed as Ectosan in 2017 and then re-branded as BMK08 in 2019). Other '[trade secrets](#)' shared by [Norwegian-owned Benchmark](#) with SEPA, the Scottish Government and the Veterinary Medicines Directorate (VMD) still remain blocked from publication.

Last week (2 July 2021), [the Norwegian Medicines Agency approved the use of Imidacloprid \(marketed now as Ectosan Vet\)](#) in salmon farming in Norway increasing pressure from Norwegian-owned companies (who [control ca. 80% of 'Scottish' salmon farming](#)) to use the [banned neonicotinoid](#) in Scotland.

Last month (9 June 2021), the [European Parliament voted to oppose the use of Imidacloprid in salmon farming](#) blocking a key market for farmed salmon and raising serious questions about the

future of Benchmark's toxic investment. The [objection to Imidacloprid use in farmed salmon from MEPs](#) focused on the lack of transparency and scientific concerns over the use of environmental impact of the [banned neonicotinoid – dubbed 'Novichok for insects' by Professor Dave Goulson of the University of Sussex](#).

In May 2021, [The Ferret revealed](#) that the Director of Marine Scotland was still backing the controversial deployment of Imidacloprid in Scottish salmon farming. A FOI disclosure by the Scottish Government in May 2021 detailed damning documents on ["the biggest con trick since Harry Houdini"](#).

"This FOI disclosure offers a shocking insight into how Government agencies conspired to bend regulatory laws to permit a banned neonicotinoid to be used in Scottish salmon farming," said Don Staniford, [Director of Scottish Salmon Watch](#) and [author of 'Silent Spring of the Sea'](#). "Reading between the heavily redacted lines it seems that Scottish Government minister Fergus Ewing bullied and lobbied for SEPA and Marine Scotland to open the floodgates to Imidacloprid. The signing of a non-disclosure agreement and marking of documents as 'Commercially Sensitive' has sadly served to keep some 'trade secrets' out of the public domain. However, last month's vote in the European Parliament against the use of Imidacloprid in salmon farming offers hope that the European Commission and other government bodies will ban this toxic chemical – dubbed 'Novichok for insects' – in salmon farming as it has already been banned in terrestrial farming."

"I am pleased to say that my Resolution objecting to the potential use of the toxic neonicotinoid 'imidacloprid' in salmon farming was passed by the European Parliament," [said Grace O'Sullivan MEP who spearheaded opposition to Imidacloprid use in salmon farming](#). "The Parliament has now officially announced its opposition to the use of these dangerous chemicals in our seafood production. Now it is up to the Commission to act on this democratic decision. The companies behind the use of Imidacloprid must come clean and share publicly any environmental risk assessments and scientific results from their field trials on salmon farms in Norway and any other countries. The solution to toxic chemical pollution is not dilution."

Pressure is building for the Scottish Government to ban the use of Imidacloprid in salmon farming. Here's an email to Scottish Ministers dated 7 June 2021 from Nick & Sue Domminney:

nick.domminney@btinternet.com
to scottish.ministers ▾

Mon, Jun 7, 9:02 PM

Subject: SCOTTISH GOVERNMENT POTENTIAL APPROVAL OF CLEAN TREAT SALMON FARM INSECTICIDE: IMIDACLOPRID

Dear Scottish Government

My MSP is James Dornan, who advised me to refer my concern to Scottish Ministers. I draw your attention to [this Guardian article](#), explaining that Marine Scotland and SEPA appear minded to raise no objection to the introduction of the Clean Treat system by fish farm biocide treatment company Benchmark. We ask you to oppose this, if it comes before the Scottish Parliament.

The treatment includes the neonicotinoid based chemical, Imidacloprid. Neonicotinoids are banned in the EU (and in the UK while in the EU) but, incredibly, not for use in water, after heavy lobbying by pharma tech giant Bayer. The chemical is, nevertheless, found in animal flea treatment and has already made its way into English water courses, despite its ban in farming.

Neonicotinoids are extremely dangerous to insect life and have proved disastrous to entire ecosystems in places where they have been introduced widely, such as Japan. They are very effective against lice on industrial farmed salmon, however, which is why the big salmon farming companies, who seem to have an unhealthy grip on the Scottish Government, are desperate to use it.

The linked article summarises the issues well but I believe there are other pieces in the Scottish press and, of course, Private Eye has reported the numerous salmon farm pollutions, chemical releases, and incidents of storm-damaged cages releasing thousands of infected fish, as well as the industry's relentless efforts to expand, despite its dreadful record.

We hope that the Scottish Government ministers will decide against trialling this treatment which, we understand, may be the subject of an application by the treatment company, Benchmark.

Best regards
Nick & Sue Domminney

Here's the reply from Scottish Ministers dated 21 June 2021:

DIRECTORATE FOR MARINE SCOTLAND
DMARINE : Aquaculture and Recreational Fisheries



Scottish Government
Riaghaltas na h-Alba
gov.scot

Sue Domminney
nick.domminney@btinternet.com

Our Reference: 202100212642

21 June 2021

Dear Sue Domminney,

Thank you for your enquiry of 07 June 2021 regarding the use of the imidacloprid on fish farms on behalf of your constituent. As I have been asked to respond, I'd like to take the opportunity to correct recent media reporting that the way is being paved for its use and reassure you, that this is not the case.

Imidacloprid is not currently authorised for use in aquaculture in the UK. Veterinary medicines are a reserved matter and require authorisation for sale and supply in the UK from the Veterinary Medicines Directorate (VMD) following robust and rigorous assessment. In addition to any authorisation granted by the VMD, the discharge of imidacloprid into the marine environment in Scotland would require authorisation from SEPA as an independent regulator. A discharge into the marine environment would only be authorised if SEPA were satisfied that environmental standards would not be breached. More generally, all fish farms in Scotland have to meet strict environmental standards, set out within licence, and these are regulated by SEPA with the aim of ensuring that the environmental impacts from the industry are assessed and managed safely.

SEPA has not received an application to use imidacloprid, nor has it had any pre-application discussions about it.

Confusion has arisen in recent media reporting between the development by Benchmark of 'Cleantreat' which is a water purification technology used for removing sea lice medicine prior to discharge, and the use of a treatment containing imidacloprid called 'BMK08' which is developed by the same company. Benchmark has been quoted in the press as stating that it is currently focused on launching BMK08, which can be used together with CleanTreat, in Norway, and that at this time it does not have any scheduled trials for BMK08 in Scotland.

I hope this provides you and your constituent with the reassurance that there is no planned imminent

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St Andrew's House, Regent Road, Edinburgh EH1 3DG
www.gov.scot



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approval for imidacloprid use in the marine environment.

Yours sincerely

Panos Pliatsikas
ARF : Aquaculture Unit

Read more via:

[Norway Approves Banned Bee-Killing Neonicotinoid for Use on Norwegian Salmon - Scotland, Chile & Canada Next In Firing Line!](#)

[Neonicotinoid Imidacloprid Dogged by Lawsuits, Bans & Deaths - Is Benchmark's BMK08 in the doghouse or will it be unleashed?](#)

[Canadian field trials of the banned neonicotinoid Imidacloprid on salmon farms?](#)

[Norwegian Environment Agency FOI reply lifts lid on banned neonicotinoid Imidacloprid Interferencia: "Salmon Farming - Norwegian company seeks to commercialize in Chile a pesticide banned by the EU for being 'very toxic' to aquatic life"](#)

[Anyone for Norwegian Salmon Marinaded in the Banned Neonicotinoid Imidacloprid \(don't worry it's ASC-approved\)?!](#)

["EU deals potential setback to Benchmark's rollout of new sea lice treatment"](#)

[Fish Farmer: "MEPs condemn new lice treatment: who's right"](#)

["EU setback for novel lice treatment"](#)

[Breaking News: Victory in Europe - Parliament votes against the use of the toxic neonicotinoid Imidacloprid in farmed salmon!](#)

[Fish Farming Expert: "Novel lice treatment threatened by European Parliament vote"](#)

[Wave of European Opposition to Benchmark's Imidacloprid \(BMK08\) - the tide turns against neonicotinoids in salmon pharming!](#)

[European Opposition to Neonicotinoid Contamination of Farmed Salmon - is BMK08 \(Imidacloprid\) dead in the water?](#)

[The Guardian: "'Novichok for insects' may be approved for Scottish fish farms"](#)

[Who are the toxic team lurking behind Benchmark's BMK08 \(Imidacloprid\) in Scottish salmon pharming?](#)

[The Ferret: "Bee-killing pesticide treatment for fish farms backed by Scottish Government"](#)

[Cleaning Tox-Sick Scottish Salmon - Benchmark's magic trick making the banned neonicotinoid Imidacloprid disappear!](#)

Contact:

Don Staniford: salmonfarmingkills@gmail.com (email to arrange phone/video call)



Key issues uncovered via [SEPA's FOI disclosure on 7 June 2021](#):

Heavily redacted [minutes of a meeting in April 2019](#) – marked 'Confidential' – between Benchmark, SEPA, Marine Scotland and VMD stated that Benchmark “were hoping for field trials for Ectosan [Imidacloprid] in Scotland later this year (2019)” and reading between the redacted lines appears to suggest that “significant investment” would only be approved by the Benchmark board if Imidacloprid was approved for use in Scotland.

CONFIDENTIAL

Use of Ectosan and Clean Treat in the UK- Meeting 2

Meeting Location: 11th April 2019, 3.15-4.00pm, SEPA Offices, Stirling

BMK stated our case to move forwards with Clinical trials in Scotland:

- It was explained that **Reg 10(5)(e)** the CleanTreat[®] system, **Reg 10(5)(e)**
- **Reg 10(5)(e)**
- Our preferred route was **Reg 10(5)(e)**
- BMK indicated a significant investment **Reg 10(5)(e)** and that this level of investment would only be approved by the BMK board **Reg 10(5)(e)**
- BMK indicated that we were hoping for field trials for Ectosan in Scotland later this year (2019).

This initiated the discussion around the licenses, those issued by Marine Scotland and those by SEPA. MS Licenses wellboats for their discharges, while SEPA issues CAR (controlled activity regulation) licenses for the farms. MS noted that the granting of the well boat licence includes a public **notice**.

https://www.sepa.org.uk/media/34761/car_a_practical_guide.pdf

The transport of treatment water **Reg 10(5)(e)** was raised:

- Marine Scotland looked at the discharge **Reg 10(5)(e)** This needs to be clarified by the MS legal department.
- **Reg 10(5)(e)**
- **Reg 10(5)(e)**
- **Reg 10(5)(e)**
- **Reg 10(5)(e)**

This document, and the information contained within it, is commercially sensitive and therefore strictly confidential. It is intended solely for Marine Scotland (MS), Scottish Environment Agency (SEPA) and the Veterinary medicines Directorate (VMD, for the purpose of clarifying the operation of Benchmark's CleanTreat Technology and the product Ectosan. You are hereby notified that any disclosure, copying, distribution or taking action in relation to the contents of this material, without the prior written permission of Benchmark Animal Health Ltd, is strictly prohibited and infringes the intellectual property rights of Benchmark Animal Health Ltd

The document – described as “commercially sensitive and therefore strictly confidential” with the warning that “any disclosure, copying, distribution or taking action in relation to the contents of this material, without the prior written permission of Benchmark Animal Health Ltd, is strictly prohibited and infringes the intellectual property rights of Benchmark Animal Health Ltd” – detailed the “need for further clarity on the subject and that MS (Marine Scotland) and SEPA legal teams would need to be involved in drafting a licence to allow CleanTreat at an approved site” with a “discussion regarding what other countries are doing and SEPA indicated that they have been talking to Canada and Norway and their interpretation of OSPAR regulations and the London Convention”.

CONFIDENTIAL

- It was agreed that there was a need for further clarity on the subject and that MS and SEPA legal teams would need to be involved in drafting a license to allow CleanTreat® at an approved site
- **Req 10(5)(e)**

There was discussion regarding what other countries are doing and SEPA indicated that they have been talking to Canada and Norway and their interpretation of OSPAR regulations and the London Convention:

<https://www.ospar.org/>

<http://www.imo.org/en/OurWork/Environment/LCLP/Pages/default.aspx>

indicated he would like to discuss with NoMA their approach to the trials already being undertaken in Norway.

In order to move forward, BMK agreed to provide more detailed information on the trial plans, the validation of the CleanTreat®, the validation of the **Req 10(5)(e)** and the draft ERA for Norway.

[Note that in May 2020, [Scottish Salmon Watch revealed that Mowi lobbied SEPA in March 2020 to support a field trial of Imidacoprid in Loch Ailort near Fort William](#)]

The ‘[Confidential](#)’ [minutes of the April 2019](#) meeting between Benchmark, SEPA, Marine Scotland and VMD also discussed “the issue of the confidentiality of any data/methods provided outside of the official field trial application” with SEPA indicating that “all correspondence must be marked commercially sensitive and confidential” so that “they can refuse any Freedom of Information (FOI) requests on commercial sensitivity grounds”.

The issue of the confidentiality of any data/methods provided outside of the official field trial application was discussed. SEPA indicated that all correspondence must be marked commercially sensitive and confidential. If this is the case, they can refuse any freedom of information (FOI) requests based on commercial sensitivity grounds. SEPA regularly refuse FOI requests on this basis.

In August 2019, an [email from a Member of the Scottish Parliament](#) who describes themselves as ‘Aquaculture Minister’ (understood to be [Fergus Ewing](#) who was the Cabinet Secretary for the Rural Economy up to May 2021) said it was “hugely disappointing” that Benchmark was trialling Imidacloprid in Norway and “see what the barriers to trialling in Scotland have been and see about overcoming these barriers as a matter of urgency”:

From: [@parliament.scot](#)
Sent: 22 August 2019 14:19
To: Cabinet Secretary for the Rural Economy <CabSecRE@gov.scot>
Cc: [@gov.scot](#)
Subject: Early Meeting with Benchmark

An early meeting was requested by Benchmark and I agreed. Can this be set up at their Edinburgh office please.

They are trialling their new vessel in Norway which is hugely disappointing. They do however want to do this in Scotland, and therefore purpose of the meeting is to go over the position and see what the barriers to trialling in Scotland have been and see about overcoming these barriers as a matter of urgency.

This is sensitive as we are in my opinion exposed now for failing to enable the trialling of the Cleantreat system here - but we have the chance to put that right. Benchmark picked up the innovation awarded at Aquanor - and this is effectively the awarded for the best innovation in the world in Aquaculture. If successful, it has the potential to be game changing and help us overcome the negative press and answer even more effectively the persistent critics of the sector.

As aquaculture Minister I need to be able to see the worlds greatest innovator innovate here and not only in Norway!

Another [email from SEPA in October 2018](#) (understood to be from Douglas Sinclair who operates out of SEPA’s Orkney office) refers to Benchmark’s “arrogance” (‘nativity’ should presumably read ‘naivety’) in reply to the drafting of ‘Commercially Sensitive’ Minutes of a meeting:

From:
Sent: 24 October 2018 09:26
To:
Subject: RE: COMMERCIALLY SENSITIVE - Minutes for Benchmark
Attachments: DRAFT_COMMERCIAL_Minutes of BAHL SEPA VMD and MS joint meeting on Ectosan and Clean Treat.DS.docx

I have not suggested any changes other than noting in the attendees list that I was only present for the first hour and given that much of that was taken up with technical challenges, might explain why I have no comments to make! The minutes do seem to expose a degree of nativity (being kind) or arrogance on the part of the company hopefully SEPA and the VMD will get what is required in order to come to a suitable position on these proposals.

Scottish Environment Protection Agency
Orkney Office
Norlantic House
KIRKWALL
Orkney
KW15 1GR

An [email from an unnamed person at the Scottish Government \(Environmental Quality and Circular Economy Division\) in November 2018](#) detailed a request from Fergus Ewing on current progress of Benchmark's application for field trials of CleanTreat and Ectosan (Imidacloprid) in Scotland with Marine Harvest (Mowi) wishing to "push forward with trials in Scotland" and wanting "to get this off the ground as soon as possible". "Progress with regulators was slow and that they wished to speed things up" said the request from Fergus Ewing who met with Benchmark earlier in 2018.

From:
Sent: 29 November 2018 10:02
To:
Cc:
Subject: Aquaculture - CleanTreat

Hi

1. I understand [redacted] passed on Mr Ewing's request for details about outstanding CAR applications – grateful for an update please.
2. We have also had a request from Mr Ewing for information about the situation regarding the following:

"Mr Ewing would like advice from SEPA + MS LOT on the current progress of Benchmark's application for field trials of CleanTREAT + Ectosan in Scotland. For those who are not aware of the system - CleanTREAT is a system which 'cleans' the sea lice treatment chemical (in this case a new product Ectosan) from water before the water is discharged. <http://www.benchmarkplc.com/articles/cleantreat-by-benchmark/> .

[redacted] outlined that the company wish to push forward with trials in Scotland (trials already happening in Norway) – and that Marine Harvest [redacted] as partner wants to get this off the ground as soon as possible. It was claimed that neither SEPA nor MS LOT could confirm to the company who the regulatory lead on their application would be. [redacted] said that progress with regulators was slow and that they wished to speed things up. Hence Mr Ewing's request for immediate advice."

Happy to discuss – by phone if appropriate

Thanks

Environmental Quality and Circular Economy Division - Environment and Forestry Directorate -
Scottish Government

In August 2019, [an unnamed Scottish Government official wrote to an unnamed individual](#) (presumably it was directed to SEPA – perhaps [SEPA's chief executive Terry A'Hearn who has been successfully lobbied in the past with respect to condoning the continued use of toxic chemicals](#)) asking "whether the discharge constitutes 'pollution', in terms of substances in the maritime area which result in harm to living resources and marine ecosystems, or whether the

output is sufficiently clean as to not constitute ‘pollution’ following the treatment of the water in the CleanTreat system”:

From: @gov.scot
Sent: 20 August 2019 13:46
To:
Cc: @gov.scot; @gov.scot; @gov.scot
Subject: RE: Assessments for Benchmark proposal

Hi ,

I hope this email finds you well.

We are trying to finalise our thinking on the licensing implications. We have been asked whether the discharge constitutes ‘pollution’, in terms of substances in the maritime area which result in harm to living resources and marine ecosystems, or whether the output is sufficiently clean as to not constitute ‘pollution’ following the treatment of the water in the cleantreat system. In terms of chemical pollution, MS seeks SEPA’s advice on this issue before we can conclude our considerations. Benchmark has submitted an ‘Overview of the Practical Operation of CleanTreat® in Scotland’, sent to SEPA by benchmark on 7th June, which provides some details on the activity and we understand you’ve also seen the draft ERA during a meeting between yourselves and Benchmark. As requested below, if more is needed for SEPA to be able to consider this, please can you let us know?

We understand that the trial in Norway was granted the necessary permissions to allow it to go ahead on the thinking that the proposal did not constitute pollution.

Can I ask you to consider this aspect and let us know as you soon as possible please?

In September 2019, [an unnamed Scottish Government official said in an email](#) that they were “asked to work with SEPA to provide the background in a brief to Cab Sec” (Cabinet Secretary for Rural Economy, Fergus Ewing):

From: @gov.scot
Sent: 12 September 2019 10:10
To:
Cc: gov.scot; @gov.scot
Subject: RE: benchmark: next steps
Attachments: ATT00003.txt

Dear ,

I have been asked to work with SEPA to provide the background in a brief to Cab Sec and our director has requested that this includes some read across to what happened in Norway, insofar as we know:

- when did they approach Norway,
- how quickly did Norway ok it,
- why any concerns we hold were not of such great import to Norway etc.

The [email from the Scottish Government dated 12 September 2019](#) admitted that “field trials were permitted in Norway with a level of discharge that appears to be above the EQS”:

What is clear is that field trials were permitted in Norway with a level of discharge that appears to be above the EQS. [Could you please provide a narrative for inclusion in the brief around SEPA’s concerns with what has been proposed?](#) It would be my intention to provide this information alongside the detail requested below around the list of requirements to try to map out any application process for benchmark.

I have been asked to provide a timeline for the approval process. Obviously this will be dependent on the provision of the right information from benchmark. Marine licence applications usually take 12 weeks to process and so a time line in that regard is simple. However, I really need to get an answer to the OSPAR question and so would really appreciate a response to the ‘pollution’ question.

In March 2019, [Benchmark emailed SEPA](#) stating that “it would be prudent to have a NDA agreement in place between Benchmark and the Scottish Government”:

From: @bmkanimalhealth.com>
Sent: 14 March 2019 13:25
To:
Cc: @gov.scot;
Subject: Finalisation of the intercompany minutes between Benchmark/SEPA/Marine Scotland/VMD
Attachments: Minutes_of_BAHL_SEPA_VMD_and_MS_joint_meeting_on_Ectosan_and_Clean_Treat_VMD and MS COMMENTS.docx

Dear SEPA,

Please find attached the minutes from the intercompany meeting held in October 2018. These contain comments from the VMD and Marine Scotland. Could I ask that SEPA review the minutes and add any additional comments?

We would like to move forward with our ATC application for a field trial in Scotland in 2019. In order to do this we would like to further discuss the data required for the Environmental Risk Assessment (ERA) and the use of CleanTreat as a mitigation measure to ensure we can discharge the cleaned treatment water in compliance with the local legislation. To facilitate this we propose to prepare a data pack providing detailed information on the use of CleanTreat, the purification method and the discharge levels prior to the ATC submission. We would like to use this disclosure to obtain a clear view of the path we should take for preparing the ERA for Scotland and for obtaining the permits to discharge the treatment water.

In order to do this outside the ATC application we feel it would be prudent to have a NDA agreement in place between Benchmark and the Scottish government. Discussions regarding this have been initiated by at Benchmark and at Marine Scotland.

Please could you indicate if you are ready to participate in these discussions.

Kind Regards

Animal Health Division



Bush House, Edinburgh Technopol, Edinburgh, EH26 0BB

In May 2019, the Scottish Salmon Producers Organisation (the lobby group whose members include [Norwegian-owned Mowi](#) who [asked the Aquaculture Stewardship Council in February 2019 for an 'interpretation request' on the use of Imidacloprid](#) – inadvertently leading to the public disclosure [naming BMK08/Ectosan as Imidacloprid in March 2020](#)) stepped up lobbying for field trials of Imidacloprid in Scotland via a [letter to SEPA](#) copied to Scottish Ministers.



30 May 2019

Mr T A'Hearn
SEPA
Strathallan House
Castle Business Park
Stirling
FK9 4TZ

By Email

Dear Terry,

Outwith scope

In this context, you undertook to look again at the potential for trials of novel lice treatment methods and the barriers in the way of Scottish trials for the CleanTreat innovation which the developers believe has no environmental impact at sea. The novel approach has been trialled in Norway successfully and now requires field trials in Scotland. It has the potential to reduce other medicinal treatment methods for lice significantly and reduce environmental impact from farms. We understand that there have been discussions with the company involved though no progress has been made to take forward trials in Scotland. If you required further information on the detail of the issue, we can provide it, though your team have worked with _____ at Marine Scotland and the company involved directly already.

Outwith scope

I am copying this letter to Roseanna Cunningham, Cabinet Secretary for Cabinet Secretary for Environment, Climate Change and Land Reform and Fergus Ewing, Cabinet Secretary for the Rural Economy.

I look forward to your early response.

Yours sincerely,

Julie Hesketh-Laird
Chief Executive

c.c. Roseanna.Cunningham.msp@parliament.scot
Fergus.Ewing.msp@parliament.scot

An [email from an unnamed Scottish Government official at the Marine Laboratory in Aberdeen to Benchmark in July 2019](#) asked for more detail on discharges of Ectosan (Imidacloprid) and “effluent water”:

(MARLAB)
Sent: 02 July 2019 16:19
T (MARLAB) <| bmkanimalhealth.com>; @sepa.org.uk>;
@gov.scot>; @vmd.defra.gsi.gov.uk>;
@SEPA.org.uk>
@bmkanimalhealth.com>;
@bmkanimalhealth.com>; @bmkanimalhealth.com>;
@bmkanimalhealth.com>; @gov.scot>;
@gov.scot>
Subject: RE: Commercially Sensitive and Confidential: White paper on use of Clean Treat in field trials in Scotland

Dear I

Thank you for the documentation submitted.

As you know, there are some regulatory questions to close off, in addition to the ongoing technical discussion. At the meeting at SEPA's office you proposed the submitted 'white paper' to provide the detail on the discharge to sea to enable MS to consider the regulatory pathway, whilst the technical discussion proceeded between Benchmark and SEPA, as the statutory consultee to the marine licensing process.

The consideration of the regulatory questions is ongoing. However, the application of marine licensing rules to your proposal is in relation to the actual discharge to sea. Your 'white paper' doesn't seem to provide sufficient detail on how that would happen, the interaction of the vessels, the transfer of effluent water and how and where the cleantreat vessel would undertake any discharge activity, for us to come to a view. I'm not able to find the required level of detail in the paper submitted to us by Benchmark titled 'Benchmark Animal Health Limited Ectosan® & Cleantreat, Effective Sea Lice Treatment with Proven Prevention of Environmental Impact, for Field Trials in Scotland' either.

As I have asked before, what we really need to know for our consideration of the regulatory questions is:

- What is being discharged to sea?
- Where is this taking place?
- What is the pathway of the effluent water Reg 10(5)(e)

If you had any information in relation to how your trial was permitted in Norway.

In September 2019, [an unnamed Scottish Government official at the Marine Laboratory in Aberdeen wrote to SEPA](#) detailing supporting information still required by Benchmark to conduct a trial of Imidacloprid in Scotland including “any physical mechanism by which

Benchmark could demonstrate meeting the EQS by techniques to enhance dilution to an acceptable level”; “details relating to fate and behavior, in particular persistence in the environment, recognizing the receiving environment in Scotland” and “an assessment of any effects upon other receptors (such as fishing interests, wild fish interests and the features of any designated sites proximal to the proposed locations)”:

I understand the supporting information should be as follows (can you please advise if I have got this wrong, or have missed anything?):

1. Recognising the **Reg 10(5)(e)** from the Netherlands in freshwater, evidence of how the discharge (or effluent at the edge of the mixing zone) will meet that.
2. Any physical mechanism by which Benchmark could demonstrate meeting the EQS by techniques to enhance dilution to an acceptable level.
3. Details relating to fate and behaviour, in particular persistence in the environment, recognising the receiving environment in Scotland.
4. Evidence to be provided to meet certain European standards – perhaps you could help phrase that?
5. A trial methodology in order to show adequate testing by acceptable methods to ensure that discharge is within acceptable levels.
6. Details of the expected breakdown products
7. a Best Practicable Environmental Option assessment report documenting the consideration of other options for handling.
8. information on the hydrography of the intended discharge location
9. perhaps an assessment of any effects upon other receptors (such as fishing interests, wild fish interests and the features of any designated sites proximal to the proposed location).

I understand that SEPA has already asked Benchmark for some of the above, so please can you advise what has been supplied and how it falls short of the required detail.

In April 2019, referring to a ‘Confidential’ meeting, [Benchmark itemized various questions](#):

Ewan has the following areas he would like to discuss specifically to ensure the ERA provided with the field trial is fit for purpose and allows assessment of the field trial application in the allotted timeframe.

- Do we need to produce a version of the ERA that uses solely UK (Scottish) aquaculture sites?
- Will SEPA/Marine Scotland/VMD accept the RIVM EQS values?
- What other supporting environmental data/reports/evidence is required; e.g. sediment studies and any associated modelling to do with its sedimentary degradation and dispersion. Guidance would be appreciated here.

[Note that Ewan may be Ewan Gillespie who formerly worked for SEPA before leaving to join Marine Harvest and then Benchmark – read more [online here](#)]

Another [email from an unnamed person at Marine Scotland in August 2019](#) reported that an unnamed person (believed to be Fergus Ewing) “met with Benchmark quite a while back”.

Sorry for the further email. Just to add (and now coping EQD) met with Benchmark quite a while back/ when they first wanted to describe the system and a submission was provided on where we were at request.

I think it would be helpful if another submission on current status from MSLOT/ EQD/ SEPA went to prior to the meeting, rather than having to respond post meeting with Benchmark.

We will also need to make sure the right people in the room and provide briefing for the meeting.

An [email from an unnamed Scottish Government official in October 2019 to SEPA](#) reported that Benchmark had “asked for a timeline for the process” and “written advice”. “Issues upon which clarity was sought in writing” included “Can the discharge location be away from site?” and “What is the modeling requirement and why?”. “We therefore collectively need to come to a view on what constitutes pollution and, if this involves a level beneath which we can conclude a discharge is not a pollution, we need to advise on the level and the location at which this should be determined i.e. can we permit a mixing zone” replied the unnamed Scottish Government official (in an email marked: “If you are not the intended recipient please destroy the email”).

From: @gov.scot
Sent: 03 October 2019 12:33
To:
Cc: @gov.scot; @gov.scot; @gov.scot; @gov.scot
Subject: request for written advice from SEPA
Attachments: RE: Assessments for Benchmark proposal

Benchmark recently raised that, whilst there had been advice given to them to date, the advice had not been in writing. They also asked for a timeline for the process. They considered that written advice would be advantageous and requested that of both MS and SEPA. There has been good dialogue to date and the issues upon which clarity was sought in writing were:

1. Can the discharge location be away from site?
2. What is the modelling requirement and why?
3. What are the time scales for provision of this information? (can we agree a timeline in more detail?)

1. The discharge location is dictated by whether or not MS-LOT can license the proposed activity. We understand that we can do this, as long as the discharge is not pollution, and we have asked SEPA this question before (attached email relates). We therefore collectively need to come to a view on what constitutes pollution and, if this involves a level beneath which we can conclude a discharge is not pollution, we need to advise on the level and the location at which this should be determined. I.e. can we permit a mixing zone? MS-LOT therefore requests that SEPA advise on the level and location at which the level should be measured. Can SEPA please respond to this request by Friday 11th Oct? Please also confirm if the mixing zone approach and the proposed draft EQS are acceptable at this time?
2. SEPA had advised Benchmark that hydrodynamic modelling will be required and that SEPA could provide some existing models for certain locations where this has been done. Can SEPA supply a list of these locations and offer the models in writing? MS-LOT can administer a response to Benchmark if required.
3. MS-LOT would like to draw up a suitable timeline and proposes that we work to a date of mid-October to be able to provide the above information. As the above can be determined by MS and SEPA without input from Benchmark. Please can you advise if any of the above requires anything further from Benchmark?

Once we have confirmed what we believe to constitute pollution we can communicate this to Benchmark and they can work on the necessary assessment to show how they could comply with that. At that time it would seem appropriate to communicate a detailed time line to them. I have pulled together a draft timeline to get your thoughts on the aspects against which SEPA is identified and whether or not there are any additions. If you're roughly content, I can pull together precise dates and share with Benchmark.

- | | |
|------------------|--|
| 1. Early Oct- | SEPA/MS Agree timeline and position on what constitutes pollution |
| 2. Early Oct- | Benchmark identify suitable locations |
| 3. Early Oct- | SEPA supply list of models to Benchmark |
| 4. Early Oct- | MS-LOT and SEPA to inform Benchmark in writing of all information required to support an application |
| 5. Mid Oct- | SEPA advise on acceptability of revised EQS |
| 6. End Oct- | Benchmark demonstrate ERA, meeting EQS, modelling on a specific location, levels of discharge and levels of mixing |
| 7. Mid Nov- | SEPA advises MS on whether levels proposed by Benchmark constitute pollution |
| 8. Early Dec- | MS considers legal advice to date based on updated advice and evidence |
| 9. Early Dec- | MS-LOT determines if a licence can be administered |
| 10. Mid Dec- | Benchmark submits licence application |
| 11. Early April- | MS-LOT determination |

Any application to deposit in the sea should be accompanied by an assessment of other practicable alternatives. MS-LOT does not regulate discharges of this nature from land and so I would appreciate SEPA's view on whether or not land based use of the cleantreat system would be a suitable alternative to vessel based discharge, in the event that we are not able to license the activity.

Happy to discuss if you wish but I would be grateful if you could respond in writing.

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[Note: The last paragraph – namely: “Any application to deposit in the sea should be accompanied by an assessment of other practicable alternatives. MS-LOT (Marine Scotland – Licensing Operations Team) does not regulate discharges of this nature from land and so I would appreciate SEPA’s view on whether or not land based use of the CleanTreat system would be a suitable alternative to vessel based discharge, in the event that we are not able to license the activity” – illustrates how Benchmark is looking to discharge Imidacloprid wastes into Scottish waters and how the Scottish Government was aiding and abetting that pollution.]

Remember that back in March 2019, [Benchmark emailed SEPA](#) expressing their desire to “move forward” with an application for a field trial in Scotland in 2019 of Imidacloprid ([marketed as Ectosan from December 2017](#) and then [re-named BMK08 in November 2019](#) before Benchmark [admitted in March 2020 that it was Imidacloprid](#)). “In order to do this we would like to further discuss the data required for the Environmental Risk Assessment (ERA) and the use of CleanTreat as a mitigation measure to ensure we can discharge the cleaned treatment water in compliance with the local legislation,” said Benchmark.

We would like to move forward with our ATC application for a field trial in Scotland in 2019. In order to do this we would like to further discuss the data required for the Environmental Risk Assessment (ERA) and the use of CleanTreat as a mitigation measure to ensure we can discharge the cleaned treatment water in compliance with the local legislation. To facilitate this we propose to prepare a data pack providing detailed information on the use of CleanTreat, the purification method and the discharge levels prior to the ATC submission. We would like to use this disclosure to obtain a clear view of the path we should take for preparing the ERA for Scotland and for obtaining the permits to discharge the treatment water.

In order to do this outside the ATC application we feel it would be prudent to have a NDA agreement in place between Benchmark and the Scottish government. Discussions regarding this have been initiated by [redacted] at Benchmark and [redacted] at Marine Scotland.

An [agenda for a meeting on 20 September](#) (believed to be in 2019 between Benchmark, SEPA, the Scottish Government and the VMD) detailed a series of outstanding questions relating to the use of Imidacloprid in Scottish salmon farming including “persistence in marine environment” and “modeling of post-initial mixing dispersion” and “what quantities will be released”.

Meeting

Friday 20th September

- 1. Introduction & purpose of meeting**
- 2. What substances will be released into the environment (including breakdown products)?**
What’s known; what would be needed to support an application
- 3. By what routes will the substances be released into the environment (eg effluent discharge; solid wastes from effluent processing; fish scale; fish excreta)?**
What’s known; what would be needed to support an application

- 4. What quantities will be released (by each route)?**
What's known; what would be needed to support an application

- 5. What operational controls will be used to check and ensure that no more than those quantities are released (management of treatment process breakdowns, etc)?**
What's known; what would be needed to support an application; opportunity to visit the current vessels (wellboat & clean treat vessel) undertaking trials in Norway

- 6. How will the substances mix and disperse in the environment?**
 - a) Partitioning of substances between water column and sediments
 - b) Persistence in marine environment
 - c) Understanding of initial mixing (buoyancy; pumping vs passive, depth, etc)
 - d) Modelling of post-initial mixing dispersion (time period, scale and type of modelling)

- 7. What are the predicted no effects concentrations (water & sediment standards, unless partitioning information shows one is negligible; type of information accepted)?**
What's known; what would be needed to support an application

- 8. What are our regulatory roles and what do you need to do to apply (OSPAR; current roles; how roles are expected to change)?**

- 9. What are your plans and timelines (purposes of any trial; identification of the specific test site; single vs multiple locations; duration; timing of applications; etc)?**

The Scottish Government and SEPA [knew as early as October 2018](#) that Ectosan was Imidacloprid (the VMD may have known earlier). 'Confidential' minutes of a meeting with Benchmark presented "results of the field testing of the product in Norway" with data on efficacy, safety and residues shared with SEPA, VMD and the Scottish Government.

CONFIDENTIAL

Use of Ectosan and Clean Treat in the UK- Final Meeting Minutes

Meeting: 9th October 2018, 1-3.30pm, BAHL, Bush House, Edinburgh

Initial discussions prior to an ATC application in the UK to test Ectosan under field conditions.

Minutes of the meeting between Benchmark Animal Health Ltd (BAHL), Scottish Environmental Protection Agency (SEPA), Veterinary Medicines Directorate (VMD) and Marine Scotland (MS)

Attendees:

BAHL:

SEPA: present for first hour only)

MS:

VMD:

BAHL provided an overview of Ectosan (active substance imidacloprid), the results of *in vitro* and *in vivo* laboratory studies, and the results of field testing of the product in Norway.

Data on efficacy, safety and residues were shared.

Note that Fish Farmer [reported in February 2020](#):

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.

However, there have been no trials of the products in Scotland yet, due to regulatory bottlenecks. The slow pace of Scottish bureaucracy emerged during the Aqua Nor show in Trondheim last August, when Benchmark won the coveted Innovation Award for CleanTreat.

Marshall and head of CleanTreat Neil Robertson held meetings during Aqua Nor with Scotland's rural economy minister Fergus

Ewing and Graham Black, director of Marine Scotland, to try to speed up Scottish trials.

The '[Confidential](#)' minutes of the October 2018 meeting referred to “accidental discharge” and how Benchmark needed to provide further information “under a confidential agreement between all interested parties”.

Clean Treat

The CleanTreat purification system was described (although information on the method of purification was not provided).

Action: BAML to provide information on how the purification system works as part of the data package. This will need to be provided under a confidential agreement between all interested parties.

The levels of active present in the fish as they leave the well boat and subsequently excreted must be considered in order to evaluate the environmental impact (i.e. do sediment studies need to be performed in addition to the water column).

SEPA need to understand if the CleanTreat system leads to breakdown products that may also need to be evaluated. BAML **Reg 10(5)(e)** can provide further information in the confidential disclosure discussed above.

Method of quantification: SEPA stated that **Reg 10(5)(e)** would not be sufficient for validation of specificity and would need to be supported by data from **Reg 10(5)(e)** to demonstrate that the peak being assessed was specific and not arising from **Reg 10(5)(e)**

Risk mitigating measures: BAML need to demonstrate the CleanTreat system is under control in order to be considered as a risk mitigation for the ERA. The capacity of the system and understanding when to stop is an important control measure to prevent accidental discharge.

The worst-case scenarios should be identified, and limits applied to prevent use in these situation (i.e. bad weather). BAML should seek parallels with other industries where transfer of material between vessels occurs (i.e. the oil and gas industry where materials are transferred between vessels).

Legislative framework: The legal body that would have jurisdiction for the use of CleanTreat is driven by the vessel on which it is placed (e.g. well boat vs platform support vessel (PSV)). If placed on the well boat then discharge would need to be within the vicinity of the farm and Marine Scotland and SEPA may be involved. If it is used on a PSV away from the site, the legislative body is less clear. If a scenario that is analogous to an existing situation (i.e. ship to ship refuelling) can be made, this may assist in the decision making.

Action: BAML to make a proposal for the ATC trial on how the CleanTreat system would operate. This will be commented on by Marine Scotland and SEPA to advise if further regulatory bodies need to be involved

MS and SEPA suggested that the use of CleanTreat with an already approved medicine (e.g. Salmosan Vet) would be desirable as there are sites with discharge consents and modelled releases and sites already treating with well-boats. A trial could potentially utilise these existing mechanisms, assessments.

BAML would like to seek clarification on why this is seen as required, as the system has been evaluated most thoroughly for imidacloprid.

The '[Confidential meeting in October 2018](#)' also discussed "the applicability of the Water Framework Directive" and how the "RIVM 2014 review of Imidacloprid could be used as a model for developing an assessment under the WFD". "This is due to the nature of the active substance that is already on the WFD watch list for environmental protection".

Discussion on the environmental aspects

The available data on the environmental laboratory studies was provided. The applicability of the Water Framework Directive (WFD) was discussed. It was stated that the VMD and SEPA do not use the same methodologies for the assessment of environmental risk. Also the validation of WFD analytical methods usually need to meet ISO17025 to be accepted as an environmental monitoring tool. (e.g. <http://publications.jrc.ec.europa.eu/repository/bitstream/JRC99958/lbna27813enn.pdf>)

Action: SEPA could you please clarify if ISO validation is required for the method applied on the CleanTreat vessel or just for the methods used for environmental monitoring?

Post meeting note: All analysis should meet the principles of GLP/ISO which includes validation and QA/QC although full ISO17025 is not at present required under CAR for fish farm medicines.

SEPA stated that the WFD should be considered in a site-specific ERA and that the WFD methodology allows for data from all water studies published in the public domain of suitable quality to be taken into account (i.e. including freshwater studies if appropriate). The RIVM 2014 review of imidacloprid could be used as a model for developing an assessment under the WFD. This is due to the nature of the active substance that is already on the WFD watch list for environmental protection. Given that a RIVM have undertaken a WFD EQS derivation this should be able to provide an indication of how such an EQS derivation could be undertaken, although it should be noted that this does not constitute an approved environmental standard limit in the UK.

BAHL would appreciate any guidance that can be provided on the application of the WFD and RIVM report into the Ectosan ERA.

The pattern of use of the product should be taken into account; is the discharge considered to be acute (i.e. one-off or infrequent single point discharges on a site) or chronic (i.e. regular discharges over a 12 month period on a site).

The impact of sediment also should be considered if the compound is excreted from the treated fish and subsequently found in the sediment. Laboratory studies to examine how the compound is excreted (in faecal matter or other organic waste), should be performed. If this is not found, sedimentary evaluation in the ERA may not be required. Data gathered in the field may be supportive.

SEPA asked if active substance discharged into the water (after purification) would subsequently bind to organic matter in the water column and become a sedimentary deposit. BAHL would appreciate advice on how to evaluate this in the laboratory or field situation.

By the [Summer of 2019](#) there were still some outstanding “regulatory questions to close off” before a field trial of Imidacloprid could be approved:

From: | |@gov.scot |@gov.scot>
Sent: 12 September 2019 16:12
T |@vmd.defra.gsi.gov.uk; |@gov.scot; |@sepa.org.uk>; |@gov.scot;
|@vmd.defra.gsi.gov.uk; |@sepa.org.uk>
Cc: |@bmkanimalhealth.com; |@sepa.org.uk>; |@gov.scot;
|@bmkanimalhealth.com; |@sepa.org.uk>
Subject: RE: Commercially Sensitive and Confidential: White paper on use of Clean Treat in field trials in Scotland - meeting

Dear

Thanks for this, and for our discussion just now, it is helping with our consideration which we hope to finalise very soon.

As we briefly discussed, it would be good to sit down with MS (me, and possible [I copied](#)) SEPA and [copied](#)) and the VMD [copied](#)) to map out the regulatory landscape for you, the information

which is required by our advisers and look to understand the timelines involved and you have agreed that we could meet next week at your office in Edinburgh Friday (20th) at 9.00.

You asked the sort of information that we would be seeking. In terms of next steps it would be good to discuss how we can move forward on a few aspects to help you meet the information requirements for a trial and the level of detail needed to make an application to us. As we discussed, it is our current understanding that it should be possible to process a licence application if the discharge from your proposal does not constitute pollution. To that end there is a level of detail required in submissions to be made, either as pre-app or perhaps as part of a marine licence application. Such information can be discussed at the meeting but below is an outline overview of the requirements:

1. Recognising the [Reg 10\(5\)\(e\)](#) from the Netherlands in freshwater, evidence of how the discharge will meet that or any other suitable evidence for meeting acceptable EQS (you mentioned that you had some aspects to discuss on this)
2. Any physical mechanism by which you can demonstrate meeting an EQS by process or techniques to ensure discharge is within an acceptable level.
3. Details relating to fate and behaviour, in particular persistence in the environment, recognising the receiving environment in Scotland.
4. Evidence to be provided to meet certain European standards and SEPA may be able to advise further on that.
5. A trial methodology in order to show adequate processes and testing by acceptable methods to ensure that discharge is within acceptable levels.
6. Details of any expected breakdown products and toxicity.
7. any future application would need a Best Practicable Environmental Option assessment report documenting the consideration of other options for handling.
8. information on the hydrography of an intended discharge location
9. some consideration of any effects upon other receptors (such as fishing interests, wild fish interests and the features of any designated sites proximal to a proposed location).

I hope this is self-explanatory but please feel free to call and discuss if you wish.

From: @bmkanimalhealth.com>
Sent: 22 August 2019 09:21
T (MARLAB) @gov.scot>; sepa.org.uk;
(MARLAB) gov.scot> [@vmd.defra.gsi.gov.uk](mailto:vmd.defra.gsi.gov.uk) @SEPA.org.uk
Cc: @bmkanimalhealth.com>;
bmkanimalhealth.com>; @bmkanimalhealth.com>;
@bmkanimalhealth.com>; @gov.scot>;
@gov.scot>

Subject: RE: Commercially Sensitive and Confidential: White paper on use of Clean Treat in field trials in Scotland

Dear

Please find attached the response to the questions Marine Scotland raised on the white paper. It hopefully answers the question you have. If not, please don't hesitate to call me.

The key for us to move forward is how the current or pending regulatory framework influences our proposals for discharges at sea. Our preference is to be able to [Reg 10\(5\)\(e\)](#)

[Reg 10\(5\)\(e\)](#)

we need to know what is possible within the regulatory framework around the discharge.

Animal Health Division



Benchmark
Animal Health

Bush House, Edinburgh Technopole, Edinburgh, EH26 0BB

From: @gov.scot <@gov.scot>
Sent: 21 August 2019 14:48
To: @bmkanimalhealth.com>; @sepa.org.uk; gov.scot;
vmd.defra.gsi.gov.uk; SEPA.org.uk
C @bmkanimalhealth.com>;
bmkanimalhealth.com>; @bmkanimalhealth.com>;
@bmkanimalhealth.com>; @gov.scot; @gov.scot

Subject: RE: Commercially Sensitive and Confidential: White paper on use of Clean Treat in field trials in Scotland

Dear

I hope this finds you well and you had a good summer holiday.

I note that you haven't responded to the below query, we are obviously trying to provide you with an answer to the licensing question and I was after the below info to try to help that. It's the third question below in relation to where and under what circumstance the boat discharging the effluent water is proposed to carry out that activity which is key and I had imagined that might be a fairly simple question to answer.

Perhaps you could give me a call if providing the below is proving problematic?

From: @bmkanimalhealth.com
Sent: 07 June 2019 15:48
To: (MARLAB) @sepa.org.uk; (MARLAB) <@gov.scot>; @vmd.defra.gsi.gov.uk;
@SEPA.org.uk
Cc: @bmkanimalhealth.com; @bmkanimalhealth.com;
@bmkanimalhealth.com

Subject: Commercially Sensitive and Confidential: White paper on use of Clean Treat in field trials in Scotland

Dear Everyone,

Please find attached the white paper on how we would like to use our CleanTreat vessel during the field trials for Ectosan in Scotland. This paper includes information on the **Reg 10(5)(e)** and its validation. Also attached is the draft protocol for the trial we wish to perform. The draft ERA has already been shared with SEPA by and discussed in a face to face meeting.

Following your review of the attached information it would be great to get your feedback as soon as possible so we can build a roadmap to the field trial application and commencement of trials in 2019. If you need any further information please don't hesitate to contact me and we would be happy to meet to discuss this at your earliest convenience.

Kind Regards

Animal Health Division



Benchmark
Animal Health

Bush House, Edinburgh Technopole, Edinburgh, EH26 0BB

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[Note that as of July 2021 it is still not clear if a field trial in Scotland of Imidacloprid have taken place although it [seems that Imidacloprid was used secretly and illegally by Benchmark at their Marine Laboratory at Ardtoe where CleanTreat was developed from 2013](#)].



Don Staniford
@TheGAAIA



Secret Salmon - On the Trail of Imidacloprid Use in Scotland tinyurl.com/y6h55fo8 Has the toxic neonicotinoid been used illegally @WeAreBenchmark @FAIfarms at Ardtoe marine laboratory? @ScottishEPA @marinescotland @vmdgovuk @FerdOwner @MowiScotlandLtd @FergusEwingMSP #BMK08



9:59 AM · Sep 4, 2020



Don Staniford
@TheGAAIA



How much of the toxic neonicotinoid Imidacloprid (BMK08/Ectosan) has been used in Scottish salmon farming (either legally or illegally) since @WeAreBenchmark registered a patent in 2011? @SSPOsays @MowiScotlandLtd @marinescotland @vmdgovuk @scotseafarms tinyurl.com/y2vwpdkd



12:38 PM · Oct 26, 2020





Don Staniford

@TheGAAIA



Will the public be able to view environmental risk assessment data on Imidacloprid (BMK08) on the Dark Web before it is approved for use in salmon farming in Scotland? @ScottishEPA @FOIScotland



4:40 PM · Apr 18, 2021



Don Staniford

@TheGAAIA



The Antithesis of the Precautionary Principle: "SEPA have not conducted any modelling of environmental impacts or ecological risk assessments of Imidacloprid use in salmon farming" tinyurl.com/y82dksur @ScottishEPA @WeAreBenchmark @FerdOwner @vmdgovuk @marinescotland #Toxic



11:46 AM · Jun 30, 2020





Don Staniford
@TheGAAIA



SEPA refuse to disclose information on the use of the toxic neonicotinoid insecticide Imidacloprid in salmon farming citing commercial confidentiality tinyurl.com/y82dksur
[@ScottishEPA](#) [@FOIScotland](#) If disclosed it would prejudice economic interests [@WeAreBenchmark](#)
[@FerdOwner](#)



11:36 AM · Jun 30, 2020



Don Staniford
@TheGAAIA



Scottish Salmon Watch lifts the lid on Imidacloprid use in salmon farming tinyurl.com/mntan7n4
How can [@GreenerScotland](#) & [@ScottishEPA](#) authorize the use of a toxic neonicotinoid banned in terrestrial agriculture in 2018 for use in salmon farming?
[@WeAreBenchmark](#) [@FerdOwner](#)



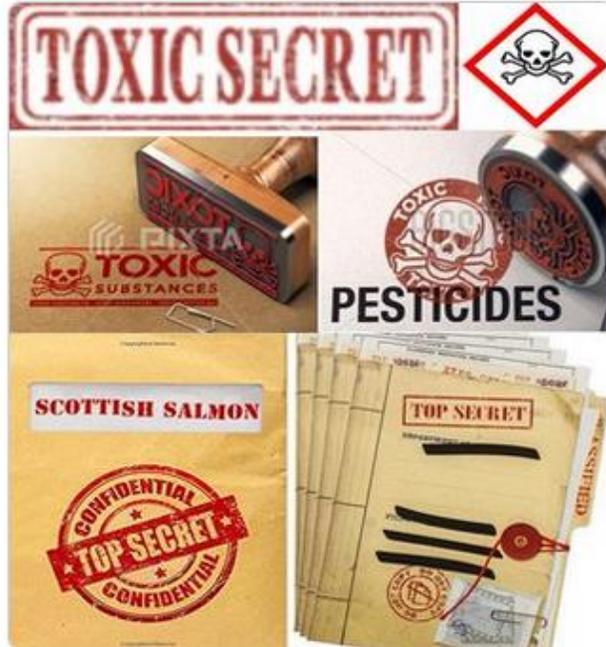
9:17 AM - Feb 24, 2021



Don Staniford
@TheGAAIA



When will Scottish salmon's toxic secrets be revealed?
Will the public discover the ecological risks of
Imidacloprid (BMK08) AFTER it has been approved?!
It's been over a year since an FOI appeal was filed!
[@FOIScotland](#) [@ScottishEPA](#) [@WeAreBenchmark](#)
tinyurl.com/dnm8f4np



7:44 AM · Apr 17, 2021



Don Staniford
@TheGAAIA



Meet the toxic team behind the use of the banned
neonicotinoid Imidacloprid in Scottish salmon pharming!
tinyurl.com/5synv5es [@WeAreBenchmark](#) [@FerdOwner](#)
[@marinescotland](#) [@ScottishEPA](#) [@MairiMcAllan](#)
[@MairiGougeon](#) [@GreenerScotland](#)
[#Imidacloprid](#) [#BMK08](#) [#Neonicotinoid](#) [#SEPA](#) [#Toxic](#)



9:37 PM · May 21, 2021



 **Don Staniford**
@TheGAAIA



To prove the safety of the neonicotinoid insecticide Imidacloprid will Scottish Ministers drink 'purified' wastewater? @WeAreBenchmark @FerdOwner tinyurl.com /ycc43zmp @FergusEwingMSP @strathearnrose @KateForbesMSP @GreenerScotland @nicolasturgeon @scotgovfm @scotgp #BMK08



1:44 PM · Jun 8, 2020



 **Don Staniford**
@TheGAAIA



Meet the filthy rich Norwegian tobacco billionaire @FerdOwner desperate to 'CleanTreat' parasite-infested farmed salmon with the toxic neonicotinoid insecticide Imidacloprid (BMK08/Ectosan) @WeAreBenchmark tinyurl.com/s3fohsb #Salmony #Salmonopoly tinyurl.com/ryqfh26



WHO WE ARE WHAT WE DO INVEST

SIGNIFICANT SHAREHOLDERS

SIGNIFICANT SHAREHOLDERS	% OF ISSUED SH
FERD AS	25.98
Kviken Finans AS	14.14
Lansdowne Partners	9.23
JNE Partners LLP	6.91
The Royal Bank of Scotland Group plc	5.80

Johan H. Andresen Jr.
Chairman of the Board of Ferd

Johan Henrik Andresen is a Norwegian industrialist and investor. Since 1998, Andresen has been the owner of Ferd, one of the largest privately held companies in Norway. He served in the position of CEO from 1998 to 2012, and has been the chairman of the board since 2012. Wikipedia

Born: 25 July 1961 (age 58 years), Oslo, Norway

Professional career (edit)

Andresen was Product Manager in International Paper Co., USA from 1989 to 1991. In 1990 he became a Partner in the New Group. He succeeded his father as the sole owner and CEO in 1998, and thus became the 10th generation of the Andresen's since the first Johan H. Andresen bought the tobacco company G. T. Tøndermanns Tabakfabrik in 1849. In 1999 the tobacco company Tøndermann was merged with the Scandinavian Tobacco Company and in 2005 Andresen sold all his shares in the company. Tøndermanns group changed its name to Ferd in 2001. Today, Ferd owns Ekip, Adair (20%), Fast Company, Ektowid and 1 companies, in addition to substantial portfolios of stock, hedge fund investments, Private Equity and property. The company's NOK 1.4 billion in 2005 to NOK 24.3 billion as of year's end 2019. In September 2019, Andresen formally attempted to acquire the Bævre packaging and former cigarette producer STI, by just 66.6% of the shares in the company. Andresen's plan was to merge STI with Ferd-owned Ekip, making it the world's second manufacturer of e-cigs, however, initiated a bidding war, and in March 2021 Ferd announced that it would no longer be pursuing. STI is one of the largest companies in Norwegian history.

1:31 PM · Mar 18, 2020



Media Backgrounder (June 2021)



[SEPA Forced to Disclose ‘Commercially Confidential’ Information on CleanTreat & BMK08/Ectosan/Imidacloprid](#)

Background: On 7 June 2021, the Scottish Environment Protection Agency (SEPA) disclosed some “commercially confidential” information on Benchmark’s CleanTreat system – including BMK08/Ectosan/Imidacloprid – following a [ruling by the Scottish Information Commissioner in April 2021](#).

SEPA [refused a FOI request from Scottish Salmon Watch in December 2019](#) prompting an [appeal to the Scottish Information Commissioner in February 2020](#).

The Scottish Government disclosed some information via FOI on CleanTreat in [December 2019](#), [July 2019](#) and [April 2018](#) but refused commercial or industrial information “where such confidentiality is provided for by law to protect a legitimate economic interest”.

SEPA [disclosed some information on CleanTreat via FOI in February, April and May 2020](#) but [refused information on BMK08/Imidacloprid/Ectosan in January and June 2020](#) claiming that “disclosure of information would cause substantial prejudice to their commercial interests”.

FOI documents: The [FOI disclosure by SEPA to Scottish Salmon Watch attached 29 PDFs](#):

[#1 FULLY DISCLOSE - Doc1\(FD\) Doc1.1\(FD\) Doc1.2\(FD\) Redacted](#)

[#2 FULLY DISCLOSE - Doc10\(FD\) Doc 10.1\(FD\) Redacted](#)

[#3 FULLY DISCLOSE - Doc11\(FD\) Doc11.1\(FD\) Doc11.2\(FD\) Doc11.3\(FD\) Redacted](#)

[#4 FULLY DISCLOSE - Doc12\(FD\) Redacted](#)

[#5 FULLY DISCLOSE - Doc13\(FD\) Redacted](#)

[#6 FULLY DISCLOSE - Doc14\(FD\) Redacted](#)

[#7 FULLY DISCLOSE -](#)

[Doc15\(FD\)Doc15.1\(FD\)Doc15.2\(FD\)Doc15.3\(FD\)Doc15.4\(FD\)Doc15.5\(FD\)Doc15.6\(FD\)Doc15.7\(FD\)Doc15.8\(FD\) Redacted](#)

[#8 FULLY DISCLOSE - Doc16\(FD\) Doc16.1\(FD\) Doc16.2\(FD\) Doc16.3\(FD\) Redacted](#)

[#9 FULLY DISCLOSE - Doc17\(FD\) Doc17.1\(FD\) Redacted](#)

[#10 FULLY DISCLOSE - Doc20\(FD\) Redacted](#)

[#11 FULLY DISCLOSE - Doc5\(FD\) Doc 5.1\(FD\) Redacted](#)

[#12 FULLY DISCLOSE - Doc5.0.1\(FD\)](#)

[#13 FULLY DISCLOSE - Doc6\(FD\) Redacted](#)

[#14 FULLY DISCLOSE - Doc7\(FD\) Redacted](#)
[#15 FULLY DISCLOSE - Doc8\(FD\) Redacted](#)
[#16 FULLY DISCLOSE - Doc9\(FD\) Redacted](#)
[#17 FULLY DISCLOSE - Doc2\(FD\) Doc2.1\(FD\) Redacted2](#)
[#18 FULLY DISCLOSE - Doc2\(FD\) Doc2.1\(FD\) Redacted](#)
[#19 FULLY DISCLOSE IN-SCOPE INFO - Doc21\(FD-InScopeInfo\) Redacted](#)
[#20 REG 10\(5\)\(E\) REDACTIONS APPLIED - Doc12.0.1\(PD\) Redacted](#)
[#21 REG 10\(5\)\(E\) REDACTIONS APPLIED - Doc12.0.2\(PD\) Redacted](#)
[#22 REG 10\(5\)\(E\) REDACTIONS APPLIED - Doc13.0.1\(PD\) Redacted](#)
[#23 REG 10\(5\)\(E\) REDACTIONS APPLIED - Doc14.0.1\(PD\) Redacted](#)
[#24 REG 10\(5\)\(E\) REDACTIONS APPLIED - Doc17.0.1\(PD\) Redacted](#)
[#25 REG 10\(5\)\(E\) REDACTIONS APPLIED - Doc3\(PD\) Doc3.1\(FD\) Redacted](#)
[#26 REG 10\(5\)\(E\) REDACTIONS APPLIED - Doc7.0.1\(PD\) Redacted](#)
[#27 REG 10\(5\)\(E\) REDACTIONS APPLIED - Doc8.0.1\(PD\) Redacted](#)
[#28 REG 10\(5\)\(E\) REDACTIONS APPLIED - Doc9.0.1\(PD\) Redacted](#)
[#29 REG 10\(5\)\(E\) REDACTIONS APPLIED - Doc4\(PD\)Doc4.1\(PD\)Doc4.2\(FD\)Doc
4.3\(PD\)Doc 4.4\(PD\)Doc 4.5\(FD\)Doc 4.6\(FD\) Doc 4.7\(FD\) Redacted](#)

Appendix: [FOI disclosure on 7 June 2021 by SEPA to Scottish Salmon Watch](#)

OFFICIAL – BUSINESS



Our Ref: 20200275/
Decision 46/2021

Mr Don Staniford
salmonfarmingkills@gmail.com

If telephoning, ask for:
Alison Mackinnon

7 June 2021

Dear Mr Staniford

INFORMATION DISCLOSED FOLLOWING ISSUE OF OSIC DECISION 46/2021

This letter is sent following the issuing of the Scottish Information Commissioner's Decision Notice 46/2021, in respect of an appeal made on behalf of Scottish Salmon Watch.

The Commissioner required SEPA to disclose to the Applicant the information he had found to have been wrongly withheld under regulation 10(5)(e) of the EIRs.

Please note that personal data has been redacted from the information to be disclosed, as the Commissioner stated that the Applicant had raised no dissatisfaction with SEPA's decision to withhold any personal data.

As requested, we are also copying confirmation of the disclosure to the investigating officer at OSIC.

If you have any queries in the meantime, please contact me.

Yours sincerely

Alison Mackinnon

Alison Mackinnon
Data Protection Officer

Cc. Wendy Snedden, Freedom of Information Officer, Office of the Scottish Information Commissioner.

Enc

OFFICIAL – BUSINESS



Chairman
Bob Downes
Chief Executive
Terry A'Hearn

Angus Smith Building

6 Parklands Avenue, Eurocentral,
Holytown, North Lanarkshire ML1 4WQ
tel 01698 839000 fax 01698 738155

www.sepa.org.uk • customer enquiries 03000 99 66 99

From: **Mackinnon, Alison** <Alison.Mackinnon@sepa.org.uk>

Date: Wed, Jun 9, 2021 at 11:56 AM

Subject: OSIC DECISION 46/2021 - DISCLOSURE OF INFORMATION - RE-SENT 9 JUNE

2021 - EMAIL 1 OF 3

To: Don Staniford <salmonfarmingkills@gmail.com>

OFFICIAL – BUSINESS

Email 1 of 3

Please note there are two versions of **Doc2(FD) Doc2.1(FD)**. In the full document ending **_Redacted.pdf**, the text of the email from 3 July 2021 13:51 has become corrupted during the transfer from Adobe. The redacted full text of the email has been recopied into the document ending in **_Redacted2.pdf**, so you can read it clearly.

I am working in a Mac and laptop and sometimes conversions don't quite work.

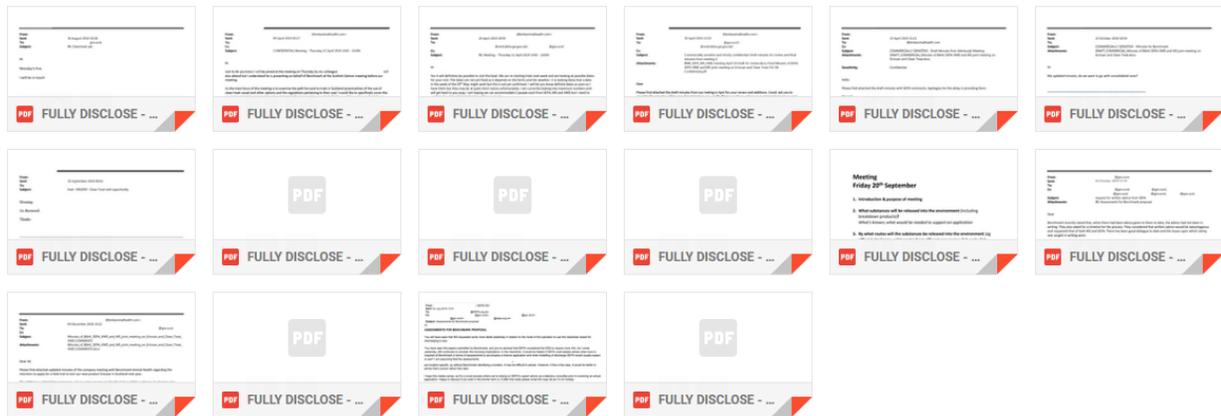
Best regards

Alison

Alison M. Mackinnon
Data Protection Officer
Scottish Environment Protection Agency
Mobile: 07795 644779

OFFICIAL – BUSINESS

18 Attachments



From: Mackinnon, Alison <Alison.Mackinnon@sepa.org.uk>

Date: Wed, Jun 9, 2021 at 11:56 AM

Subject: OSIC DECISION 46/2021 - DISCLOSURE OF INFORMATION - RE-SENT 9 JUNE 2021 - EMAIL 2 OF 3

To: Don Staniford <salmonfarmingkills@gmail.com>

OFFICIAL – BUSINESS

Email 2 of 3

Best regards

Alison

Alison M. Mackinnon
Data Protection Officer
Scottish Environment Protection Agency
Mobile: 07795 644779

5 Attachments



From: **Mackinnon, Alison** <Alison.Mackinnon@sepa.org.uk>
Date: Wed, Jun 9, 2021 at 11:56 AM
Subject: OSIC DECISION 46/2021 - DISCLOSURE OF INFORMATION - RE-SENT 9 JUNE 2021 - EMAIL 3 OF 3
To: Don Staniford <salmonfarmingkills@gmail.com>

OFFICIAL – BUSINESS

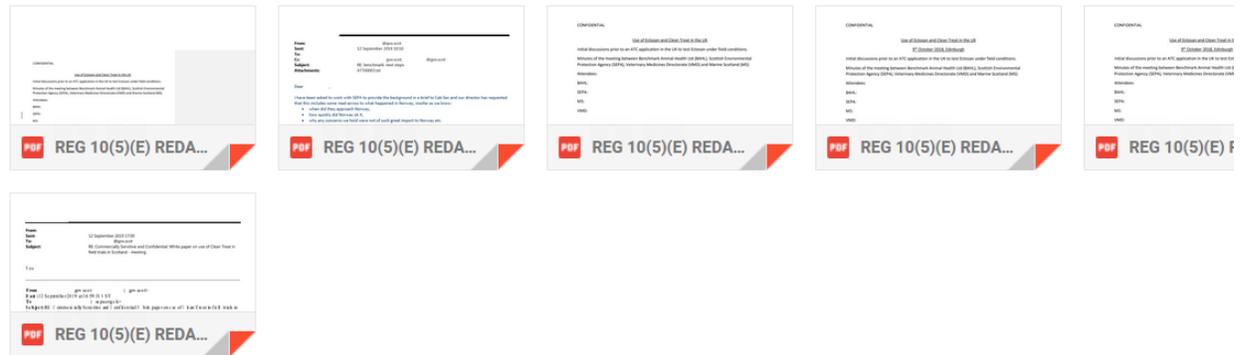
Email 3 of 3

Best regards

Alison

Alison M. Mackinnon
Data Protection Officer
Scottish Environment Protection Agency
Mobile: 07795 644779

6 Attachments



PDF #1:

From: @gov.scot>
Sent: 30 August 2019 11:08
To: (MARLAB) @gov.scot>
Cc: @sepa.org.uk @sepa.org.uk
Subject: Cleantreat sub

I have from SEPA with me today and he would be happy to offering some wording on the draft submission to help clarify SEPAs position. is it Ok for him to liaise with you on this early next week?

Environmental Quality and Circular Economy Division -Environment and Forestry
Directorate - Scottish Government

PDF #2:

From: @bmkanimalhealth.com>
Sent: 09 April 2019 09:27
To:
Cc:
Subject: CONFIDENTIAL Meeting - Thursday 11 April 2019 1430 - 1630h

Hi

Just to let you know I will be joined at the meeting on Thursday by my colleague will also attend but I understand he is presenting on behalf of Benchmark at the Scottish Salmon meeting before our meeting.

As the main focus of the meeting is to examine the path forward to trials in Scotland (practicalities of the use of clean treat vessel and other options and the regulations pertaining to their use) I would like to specifically cover the environmental risk assessment and analytical method separately, as I don't think we will have time in the 2 hours currently allocated. To this end would you be happy to attend a video or telephone conference specifically on this area (with as well) to discuss the ERA with and myself? If you are happy to attend I will discuss a possible date with and yourself on Thursday.

Ewan has the following areas he would like to discuss specifically to ensure the ERA provided with the field trial is fit for purpose and allows assessment of the field trial application in the allotted timeframe.

- Do we need to produce a version of the ERA that uses solely UK (Scottish) aquaculture sites?
- Will SEPA/Marine Scotland/VMD accept the RIVM EQS values?
- What other supporting environmental data/reports/evidence is required; e.g. sediment studies and any associated modelling to do with its sedimentary degradation and dispersion. Guidance would be appreciated here.

Looking forward to meeting on Thursday.

Kind Regards

Animal Health Division



Bush House, Edinburgh Technopole, Edinburgh, EH26 0BB

PDF #3:

From: @SEPA.org.uk>
Sent: 23 April 2019 14:49
To: @bmkanimalhealth.com>; @sepa.org.uk>;
@vmd.defra.gsi.gov.uk)' @vmd.defra.gsi.gov.uk>; @gov.scot'
@gov.scot>
Cc: @bmkholdings.com>
Subject: RE: Meeting - Thursday 11 April 2019 1430 - 1630h

Hi

Thanks for your time a couple of weeks ago. On reflection given your proposals are likely to involve commissioning a new or repurposing an existing vessel, it is important that we have the opportunity to feed in to or comment on any designs (particularly in reference to any potential process controls). As raised at the meeting our current understanding of the treatment and transfer process of your operations in Norway is fairly limited, for us to provide appropriate input we really need to have a clear understanding of the existing process. I think a visit to the existing vessel whilst operational would really help us develop that understanding. This would then allow us to highlight any areas of concern early so that they could potentially be addressed/mitigated as part of the design process.

I know there was an action from the meeting, but it would be good to know if that is going to be possible and if so, when and what limit there might be in numbers?

From: @bmkanimalhealth.com>
Sent: 26 April 2019 18:50
To: @vmd.defra.gsi.gov.uk); @gov.scot'
Cc:
Subject: RE: Meeting - Thursday 11 April 2019 1430 - 1630h

Hi

Yes it will definitely be possible to visit the boat. We are re-starting trials next week and are looking at possible dates for your visit. The dates are not yet fixed as it depends on the farms and the weather. It is looking likely that a date in the week of the 20th May might work but this is not yet confirmed. I will let you know definite dates as soon as I have them but they may be at quiet short notice unfortunately. I am currently looking into maximum numbers and will get back to you asap. I am hoping we can accommodate 2 people each from SEPA, MS and VMD but I need to confirm this. We will be limited by safety issues etc.

Kind Regards

Animal Health Division



Benchmark
Animal Health

Bush House, Edinburgh Technopole, Edinburgh, EH26 0BB

PDF #4:

From: @bmkanimalhealth.com>
Sent: 30 April 2019 22:19
To: @gov.scot';
@vmd.defra.gsi.gov.uk'
Cc:
Subject: Commercially sensitive and strictly confidential: Draft minutes for review and final minutes from meeting 1
Attachments: BMK_SEPA_MS_VMD meeting April 19 Draft for review.docx; Final Minutes of BAHL SEPA VMD and MS joint meeting on Ectosan and Clean Treat Oct 18-Confidential.pdf

Dear

Please find attached the draft minutes from our meeting in April for your review and additions. Could ask you to circulate the minutes within your department as you see fit. Please could you return your comments to me as soon as possible.

Also attached are the final minutes from the meeting last October for your records.

Kind Regards

Animal Health Division



Benchmark
Animal Health

Bush House, Edinburgh Technopole, Edinburgh, EH26 0BB

PDF #5:

From:
Sent: 23 April 2019 15:21
To: @bmkanimalhealth.com
Cc:
Subject: COMMERCIALLY SENSITIVE - Draft Minutes from Edinburgh Meeting
Attachments: DRAFT_COMMERCIAL_Minutes of BAHL SEPA VMD and MS joint meeting on Ectosan and Clean Treat.docx
Sensitivity: Confidential

Hello

Please find attached the draft minutes with SEPA comments. Apologies for the delay in providing them.

Regards

Chemistry Department

Scottish Environment Protection Agency
Strathallan House
Castle Business Park
Stirling
FK9 4TZ

PDF #6:

From:
Sent: 23 October 2018 10:54
To:
Subject: COMMERCIALLY SENSITIVE - Minutes for Benchmark
Attachments: DRAFT_COMMERCIAL_Minutes of BAHL SEPA VMD and MS joint meeting on Ectosan and Clean Treat.docx

Hi

My updated minutes, do we want to go with consolidated ones?

Chemistry Department

Scottish Environment Protection Agency
Strathallan House
Castle Business Park
Stirling
FK9 4TZ

PDF #7:

From: @SEPA.org.uk>
Sent: 24 August 2019 09:37
To: @sepa.org.uk>; @sepa.org.uk>
Cc: @sepa.org.uk>
Subject: RE: Meeting with Benchmark, OME ref: EXT05-A-F0190880, due by 30 August

Ok one of those actions are covered we have the 2 hour slot with ref AMT on the 10th. Do you think that is sufficient in terms of timeframes? Given ask are looking for a response by next Friday....

I agree we need to focus on this on Thursday. Unfortunately I can't attend on Thursday afternoon

'has been managing the agenda for Thursday if that needs changed, we need to discuss with and highlight to people, as they are all preparing (we shouldn't do that last minute). At the moment agenda is as follows, with an hour on each:

Wild fish -
Medicine -
Data reporting - and others
Scotland's Aquaculture web -

With guests invited accordingly, so and FOI are invited due to last two items. So any changes to that agenda needs done sooner rather than later and people need to be advised.

From: @sepa.org.uk>
Date: 24 August 2019 at 08:52:35 BST
To: @SEPA.org.uk>, @sepa.org.uk>
Subject: RE: Meeting with Benchmark, OME ref: EXT05-A-F0190880, due by 30 August

I think we should use the time we have on Thursday to map out a position on medicines. I developed an initial framework in the form of flow charts that has progressed with . I think we need to use this as the basis of the show and tell discussion and then prepare a draft recommended position. Once we have done this , I think we should then check in with AMT.

This would mean:

1. Making sure the right people are there on Thursday - I think are key
2. Cutting the agenda. My inclination is to make this the sole item but at any rate the number of other items really needs to be significantly thinned!

I think we then need to:

- (a) ask someone to write a draft recommendation on the basis of the discussion;
- (b) review and agree this at special ACG call; and
- (c) get a slot with Reg AMT
- (d) down with and explain

Agree this is something on which we now need to move quickly.

From: @SEPA.org.uk>
Date: 24 August 2019 at 08:36:00 BST
To: @sepa.org.uk>, @sepa.org.uk>
Subject: RE: Meeting with Benchmark, OME ref: EXT05-A-F0190880, due by 30 August

How do you want to progress the below. As you know was in Norway last week and much was made about this product from a Scottish company winning the innovation award in Norway and not being able to be used in Scotland currently. This was reiterated to me over the three days, by a number of prominent people in the industry. I did push the premise of bringing treatment system over to use with existing bath treatments and how that would be reasonably straightforward.

Thanks

From: Ask <Ask@sepa.org.uk>
Date: 23 August 2019 at 09:02:10 BST
To: @sepa.org.uk>, @sepa.org.uk>, @SEPA.org.uk>
Cc: Ask <Ask@sepa.org.uk>
Subject: RE: Meeting with Benchmark, OME ref: EXT05-A-F0190880, due by 30 August

Morning, you'll have seen the OME from regarding a briefing required for a meeting with Benchmark.

Please can you provide me with an approved response by next Friday 30 August which I'll send on to her. If needs it sooner, I'll let you know.

From: [@gov.scot](#) [@gov.scot](#)>
Sent: 23 August 2019 08:20
To: Ask <Ask@sepa.org.uk>
Cc: [@sepa.org.uk](#)>; [@sepa.org.uk](#)>;
[@SEPA.org.uk](#)>
Subject: FW: Meeting with Benchmark

Morning,

Please see attached. I will need some briefing from SEPA perspective please – date of meeting yet to be agreed but likely to be fairly soon

From: [@gov.scot](#)>
Sent: 23 August 2019 06:19
To: [@gov.scot](#)>; [@gov.scot](#)>;
[@gov.scot](#)>; [@gov.scot](#)>;
[@gov.scot](#)>; [@gov.scot](#)>;
[@gov.scot](#)>; [@gov.scot](#)>;
[@gov.scot](#)>; (MARLAB)
[@gov.scot](#)>;
[@gov.scot](#)>; (MARLAB) [@gov.scot](#)>;
[@gov.scot](#)>; [@gov.scot](#)>;
[@gov.scot](#)>; [@gov.scot](#)>;
[@gov.scot](#)>;
Subject: RE: Meeting with Benchmark

Thanks . I would endorse your suggestion given that will wish to be able to explain to Benchmark how we are progressing their application. He is clearly keen to confirm to them at the meeting that we can move forward with trialling their product so if there are any regulatory barriers to that we'll need to explain those to him before the meeting and, if that's the case, I suspect he'll want a pre-meeting with officials so we'll want briefing to go up with some time to spare ahead of the meeting.

From: [@gov.scot](#)>
Date: Thursday, 22 Aug 2019, 5:31 pm
To: [@gov.scot](#)>; [@gov.scot](#)>;
[@gov.scot](#)>; [@gov.scot](#)>;
[@gov.scot](#)>; [@gov.scot](#)>;
[@gov.scot](#)>; [@gov.scot](#)>;
[@gov.scot](#)>; (MARLAB)
[@gov.scot](#)>; [@gov.scot](#)>;
[@gov.scot](#)>; [@gov.scot](#)>;
[@gov.scot](#)>;
[@gov.scot](#)>;
Subject: RE: Meeting with Benchmark

Sorry for the further email. Just to add (and now coping EQD) met with Benchmark quite a while back/ when they first wanted to describe the system and a submission was provided on where we were at request.

I think it would be helpful if another submission on current status from MSLOT/ EQD/ SEPA went to prior to the meeting, rather than having to respond post meeting with Benchmark.

We will also need to make sure the right people in the room and provide briefing for the meeting.

Best regards

Marine Scotland – Aquaculture, Crown Estate, Recreational Fisheries, EMFF and Europe

Web: <http://www.scotland.gov.uk/marinescotland>

Mail: Scottish Government, 1B North, Victoria Quay, Edinburgh EH6 6QQ



From: @parliament.scot
Sent: 22 August 2019 14:19
To: Cabinet Secretary for the Rural Economy <CabSecRE@gov.scot>
Cc: @gov.scot
Subject: Early Meeting with Benchmark

An early meeting was requested by Benchmark and I agreed. Can this be set up at their Edinburgh office please.

They are trialling their new vessel in Norway which is hugely disappointing. They do however want to do this in Scotland, and therefore purpose of the meeting is to go over the position and see what the barriers to trialling in Scotland have been and see about overcoming these barriers as a matter of urgency.

This is sensitive as we are in my opinion exposed now for failing to enable the trialling of the Cleantreat system here - but we have the chance to put that right. Benchmark picked up the innovation awarded at Aquanor - and this is effectively the awarded for the best innovation in the world in Aquaculture. If successful, it has the potential to be game changing and help us overcome the negative press and answer even more effectively the persistent critics of the sector.

As aquaculture Minister I need to be able to see the worlds greatest innovator innovate here and not only in Norway!

PDF #8:

From: I [redacted] bmkanimalhealth.com>
Date: 25 September 2019 at 16:34:50 BST
To: [redacted] gov.scot> SEPA.org.uk [redacted] @gov.scot
Cc: [redacted] gov.scot> bmkanimalhealth.com> [redacted] bmkanimalhealth.com>
Subject: RE: URGENT- Clean Treat visit opportunity

Dear

Yes we would be happy for [redacted] to visit the boat if [redacted] is comfortable with accessing the ship via the gangway. It is not a flat walk, there is a slight camber to it. We will clear a path so [redacted] can move to the lab to see inside on the deck of the boat. A couple of points to note for you all;

The address is; Leith Docks, Bath Road Entrance, South Imperial Yard, Leith, Edinburgh EH7 6DN for approx. 08:45am

- Please bring photo ID with you to access the port
- On arrival at the port, please wait at the entrance area. Call [redacted] and he will come to meet you and escort you to Berth 4, South Imperial Yard quayside – 08:55am
- Personal Protective Equipment will be provided for you to wear. This will be a high vis jacket, hard hat and safety wellingtons. Please send me your shoe size, and that of [redacted] asap so we can provide appropriately sized boots. Enter security shelter to change into PPE – 09:00am
- You will receive a safety briefing from the boat captain and our H&S officer [redacted] for clean treat (10 minutes)
- Access will be limited to the deck of the boat only and inside of the lab
- Commence tour of CleanTreat equipment approx. 09:10am up to 09:50am – access to lab included.
- Return to Security Shelter 09:55am to return PPE, assigned driver will show the way back to security entrance or drop off where appropriate

- Please note that the lab will not be operational and will be packed for transport
- Similarly Clean Treat will not be operational. Some of the piping will have been removed to allow easier access to sections of the deck.

From: [redacted] SEPA.org.uk>
Sent: 25 September 2019 11:53
To: [redacted] @bmkanimalhealth.com>; [redacted] @vmd.defra.gsi.gov.uk>; [redacted] @gov.scot
Cc: [redacted] @bmkanimalhealth.com>; [redacted] | [redacted] bmkanimalhealth.com>
Subject: RE: URGENT- Clean Treat visit opportunity

Morning

I can make 9am on Monday, I think it is important to flag a couple of points. We would expect to follow this up with a visit to the warehouse with relevant staff (our chemists), however having spoken to [redacted], whilst a visit to the lab in a warehouse would be worthwhile it would obviously be much better to see the lab in situ on the vessel.

Given the above and the fact that [redacted] can no longer make it, would it be possible to include [redacted] on the visit? We understand that a chemist won't be available on the day, but still think [redacted] seeing the lab in situ would be of benefit.

Thanks

Scottish Environment Protection Agency, Regulatory Services North, West Highland and Argyll Team, Kilbrandon House, Manse Brae, Lochgilphead, PA31 8QX

@sepa.org.uk web: www.sepa.org.uk

From: [@bmkanimalhealth.com](mailto:bmkanimalhealth.com)>
Sent: 24 September 2019 18:12
To: vmd.defra.gsi.gov.uk>; gov.scot; I
[@SEPA.org.uk](mailto:SEPA.org.uk)>
Cc: [@bmkanimalhealth.com](mailto:bmkanimalhealth.com)>;
bmkanimalhealth.com>
Subject: URGENT- Clean Treat visit opportunity
Importance: High

Hi Everyone,

My apologies for the short notice of this but I have just heard the Clean Treat boat is coming back to Leith this weekend. If you wish to see Clean Treat on the deck of the boat there is an opportunity **at 9am on Monday morning (30th) at Leith docks**. This invitation is limited to the recipients of this email as we have H&S restrictions and cannot manage a large party of people. The Clean Treat system will be removed from the deck from lunchtime onwards. This is the last opportunity ahead of any trials in the UK, as we have now completed our planned trials in Norway. The Clean Treat system and lab will be in a warehouse after this date so could be viewed then. Please note that the tour would be given by some of our Clean Treat team but there will be no chemist available.

I you would like to visit please could you let me know by tomorrow at 5pm.

Again, sorry for the short notice.

Kind Regards

Animal Health Division



Benchmark
Animal Health

Bush House, Edinburgh Technopole, Edinburgh, EH26 0BB

[PDF #9:](#)

From:
Sent: 24 October 2018 09:26
To:
Subject: RE: COMMERCIALLY SENSITIVE - Minutes for Benchmark
Attachments: DRAFT_COMMERCIAL_Minutes of BAHL SEPA VMD and MS joint meeting on Ectosan and Clean Treat.DS.docx

I have not suggested any changes other than noting in the attendees list that I was only present for the first hour and given that much of that was taken up with technical challenges, might explain why I have no comments to make! The minutes do seem to expose a degree of nativity (being kind) or arrogance on the part of the company hopefully SEPA and the VMD will get what is required in order to come to a suitable position on these proposals.

Scottish Environment Protection Agency
Orkney Office
Norlantic House
KIRKWALL
Orkney
KW15 1GR

From:
Sent: 23 October 2018 10:54
To: @sepa.org.uk> @SEPA.org.uk>
Subject: COMMERCIALY SENSITIVE - Minutes for Benchmark

Hi

My updated minutes, do we want to go with consolidated ones?

Chemistry Department

Scottish Environment Protection Agency
Strathallan House
Castle Business Park
Stirling
FK9 4TZ

PDF #10:

From:
Sent: 29 November 2018 10:02
To:
Cc:
Subject: Aquaculture - CleanTreat

Hi

1. I understand passed on Mr Ewing's request for details about outstanding CAR applications – grateful for an update please.

2. We have also had a request from Mr Ewing for information about the situation regarding the following:

“Mr Ewing would like advice from SEPA + MS LOT on the current progress of Benchmark's application for field trials of CleanTREAT + Ectosan in Scotland. For those who are not aware of the system - CleanTREAT is a system which 'cleans' the sea lice treatment chemical (in this case a new product Ectosan) from water before the water is discharged. <http://www.benchmarkplc.com/articles/cleantreat-by-benchmark/> .

outlined that the company wish to push forward with trials in Scotland (trials already happening in Norway) – and that Marine Harvest) as partner wants to get this off the ground as soon as possible. It was claimed that neither SEPA nor MS LOT could confirm to the company who the regulatory lead on their application would be. said that progress with regulators was slow and that they wished to speed things up. Hence Mr Ewing's request for immediate advice.”

Happy to discuss – by phone if appropriate

Thanks

Environmental Quality and Circular Economy Division - Environment and Forestry Directorate -
Scottish Government

PDF #11:

From: @gov.scot
Sent: 17 September 2019 14:29
To:
Cc: @vmd.defra.gsi.gov.uk
Subject: RE: Draft Agenda for Friday
Attachments: ATT00003.txt

Hi

Thanks very much I shall send to Benchmark ahead of the meeting. I have now confirmed with them that it's 10-00 at VQ. Hope that's ok for all.

Do we have an angle in your agenda for the standards to be met in the assessments?

Happy to discuss.

Thanks

From: @sepa.org.uk>
Sent: 17 September 2019 13:28
To: @gov.scot>
Cc: @sepa.org.uk>; @vmd.defra.gsi.gov.uk> @vmd.defra.gsi.gov.uk)
Subject: Draft Agenda for Friday

Hello

Please find attached the draft agenda that and I have pulled together for Friday's Meeting. Hopefully it captures all the areas we identified at yesterday morning's teleconference that we wish to cover.

Regards

PDF #12:

Meeting Friday 20th September

- 1. Introduction & purpose of meeting**
- 2. What substances will be released into the environment** (including breakdown products)?
What's known; what would be needed to support an application
- 3. By what routes will the substances be released into the environment** (eg effluent discharge; solid wastes from effluent processing; fish scale; fish excreta)?
What's known; what would be needed to support an application

4. **What quantities will be released (by each route)?**
What's known; what would be needed to support an application

5. **What operational controls will be used to check and ensure that no more than those quantities are released** (management of treatment process breakdowns, etc)?
What's known; what would be needed to support an application; opportunity to visit the current vessels (wellboat & clean treat vessel) undertaking trials in Norway

6. **How will the substances mix and disperse in the environment?**
 - a) Partitioning of substances between water column and sediments
 - b) Persistence in marine environment
 - c) Understanding of initial mixing (buoyancy; pumping vs passive, depth, etc)
 - d) Modelling of post-initial mixing dispersion (time period, scale and type of modelling)

7. **What are the predicted no effects concentrations** (water & sediment standards, unless partitioning information shows one is negligible; type of information accepted)?
What's known; what would be needed to support an application

8. **What are our regulatory roles and what do you need to do to apply** (OSPAR; current roles; how roles are expected to change)?

9. **What are your plans and timelines** (purposes of any trial; identification of the specific test site; single vs multiple locations; duration; timing of applications; etc)?

[PDF #13:](#)

From: @gov.scot
Sent: 03 October 2019 12:33
To:
Cc: @gov.scot; @gov.scot; @gov.scot; @gov.scot
Subject: request for written advice from SEPA
Attachments: RE: Assessments for Benchmark proposal

Benchmark recently raised that, whilst there had been advice given to them to date, the advice had not been in writing. They also asked for a timeline for the process. They considered that written advice would be advantageous and requested that of both MS and SEPA. There has been good dialogue to date and the issues upon which clarity was sought in writing were:

1. Can the discharge location be away from site?
2. What is the modelling requirement and why?
3. What are the time scales for provision of this information? (can we agree a timeline in more detail?)

1. The discharge location is dictated by whether or not MS-LOT can license the proposed activity. We understand that we can do this, as long as the discharge is not pollution, and we have asked SEPA this question before (attached email relates). We therefore collectively need to come to a view on what constitutes pollution and, if this involves a level beneath which we can conclude a discharge is not pollution, we need to advise on the level and the location at which this should be determined. I.e. can we permit a mixing zone? MS-LOT therefore requests that SEPA advise on the level and location at which the level should be measured. Can SEPA please respond to this request by Friday 11th Oct? Please also confirm if the mixing zone approach and the proposed draft EQS are acceptable at this time?
2. SEPA had advised Benchmark that hydrodynamic modelling will be required and that SEPA could provide some existing models for certain locations where this has been done. Can SEPA supply a list of these locations and offer the models in writing? MS-LOT can administer a response to Benchmark if required.
3. MS-LOT would like to draw up a suitable timeline and proposes that we work to a date of mid-October to be able to provide the above information. As the above can be determined by MS and SEPA without input from Benchmark. Please can you advise if any of the above requires anything further from Benchmark?

Once we have confirmed what we believe to constitute pollution we can communicate this to Benchmark and they can work on the necessary assessment to show how they could comply with that. At that time it would seem appropriate to communicate a detailed time line to them. I have pulled together a draft timeline to get your thoughts on the aspects against which SEPA is identified and whether or not there are any additions. If you're roughly content, I can pull together precise dates and share with Benchmark.

- | | |
|------------------|--|
| 1. Early Oct- | SEPA/MS Agree timeline and position on what constitutes pollution |
| 2. Early Oct- | Benchmark identify suitable locations |
| 3. Early Oct- | SEPA supply list of models to Benchmark |
| 4. Early Oct- | MS-LOT and SEPA to inform Benchmark in writing of all information required to support an application |
| 5. Mid Oct- | SEPA advise on acceptability of revised EQS |
| 6. End Oct- | Benchmark demonstrate ERA, meeting EQS, modelling on a specific location, levels of discharge and levels of mixing |
| 7. Mid Nov- | SEPA advises MS on whether levels proposed by Benchmark constitute pollution |
| 8. Early Dec- | MS considers legal advice to date based on updated advice and evidence |
| 9. Early Dec- | MS-LOT determines if a licence can be administered |
| 10. Mid Dec- | Benchmark submits licence application |
| 11. Early April- | MS-LOT determination |

Any application to deposit in the sea should be accompanied by an assessment of other practicable alternatives. MS-LOT does not regulate discharges of this nature from land and so I would appreciate SEPA's view on whether or not land based use of the cleantreat system would be a suitable alternative to vessel based discharge, in the event that we are not able to license the activity.

Happy to discuss if you wish but I would be grateful if you could respond in writing.

 This e-mail (and any files or other attachments transmitted with it) is intended solely for the attention of the addressee(s). Unauthorised use, disclosure, storage, copying or distribution of any part of this e-mail is not permitted. If you are not the intended recipient please destroy the email, remove any copies from your system and inform the sender immediately by return. Communications with the Scottish Government may be monitored or recorded in order to secure the effective operation of the system and for other lawful purposes. The views or opinions contained within this e-mail may not necessarily reflect those of the Scottish Government.

PDF #14:

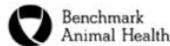
From: @bmkanimalhealth.com>
Sent: 18 October 2018 17:50
To: @gov.scot;
Cc:
Subject: Minutes from the Benchmark Company Meeting
Attachments: Minutes of BAH, SEPA, VMD and MS joint meeting on Ectosan and Clean Treat.docx

Dear All,

Please find attached our draft minutes for the meeting at Bush House on Ectosan and CleanTreat. Please could I ask you to send me any comments in track changes and I will produce a final version.

Kind Regards

Animal Health Division



Bush House, Edinburgh Technopol, Edinburgh, EH26 0BB

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PDF #15:

From: @bmkanimalhealth.com>
Sent: 04 December 2018 14:22
To: @gov.scot
Cc:
Subject: Minutes_of_BAHL_SEPA_VMD_and_MS_joint_meeting_on_Ectosan_and_Clean_Treat_VMD COMMENTS
Attachments: Minutes_of_BAHL_SEPA_VMD_and_MS_joint_meeting_on_Ectosan_and_Clean_Treat_VMD COMMENTS.docx

Dear All,

Please find attached updated minutes of the company meeting with Benchmark Animal Health regarding the intention to apply for a field trial to test our new product Ectosan in Scotland next year.

The VMD have added their comments. I have yet to receive any feedback from SEPA or Marine Scotland on the minutes. In order to progress the project we would very much appreciate your feedback on the meeting so we can begin the next steps. I would be grateful if you could add your comments to the attached document and I will prepare a consolidated final version.

Kind Regards

Animal Health Division



Bush House, Edinburgh Technopol, Edinburgh, EH26 0BB

PDF #16:

From: @bmkanimalhealth.com>
Sent: 14 March 2019 13:25
To:
Cc: @gov.scot;
Subject: Finalisation of the intercompany minutes between Benchmark/SEPA/Marine Scotland/VMD
Attachments: Minutes_of_BAHL_SEPA_VMD_and_MS_joint_meeting_on_Ectosan_and_Clean_Treat_VMD and MS COMMENTS.docx

Dear SEPA,

Please find attached the minutes from the intercompany meeting held in October 2018. These contain comments from the VMD and Marine Scotland. Could I ask that SEPA review the minutes and add any additional comments?

We would like to move forward with our ATC application for a field trial in Scotland in 2019. In order to do this we would like to further discuss the data required for the Environmental Risk Assessment (ERA) and the use of CleanTreat as a mitigation measure to ensure we can discharge the cleaned treatment water in compliance with the local legislation. To facilitate this we propose to prepare a data pack providing detailed information on the use of CleanTreat, the purification method and the discharge levels prior to the ATC submission. We would like to use this disclosure to obtain a clear view of the path we should take for preparing the ERA for Scotland and for obtaining the permits to discharge the treatment water.

In order to do this outside the ATC application we feel it would be prudent to have a NDA agreement in place between Benchmark and the Scottish government. Discussions regarding this have been initiated by at Benchmark and at Marine Scotland.

Please could you indicate if you are ready to participate in these discussions.

Kind Regards

Animal Health Division



Bush House, Edinburgh Technopol, Edinburgh, EH26 0BB

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PDF #17:

From:) (MARLAB)
Sent: 03 July 2019 13:51
To: @SEPA.org.uk>
Cc: @gov.scot>; @gov.scot>; @sepa.org.uk> @gov.scot>;
Subject: Assessments for Benchmark proposal

Hi

ASSESSMENTS FOR BENCHMARK PROPOSAL

You will have seen that MS requested some more detail yesterday in relation to the mode of the operation to use the cleantreat vessel for discharging to sea.

You have seen the papers submitted by Benchmark, and you've advised that SEPA considered the ERA to require more info. As I wrote yesterday, MS continues to consider the licensing implications. In the meantime, it would be helpful if SEPA could please advise what more is required of Benchmark in terms of assessments to accompany a licence application and what modelling of discharge SEPA would usually expect to see? I am assuming that the assessments

are location specific, so without Benchmark identifying a location, it may be difficult to advise. However, if this is the case, it would be better to advise them sooner rather than later.

I hope this makes sense, as it's a novel process where we're relying on SEPA's expert advice as a statutory consultee prior to receiving an actual application. Happy to discuss if you wish in the shorter term or, if after this week please email the copy list as I'm on holiday.

Thanks

Kind regards,

PDF #18:

From: @gov.scot
Sent: 20 August 2019 13:46
To:
Cc: @gov.scot; @gov.scot; @gov.scot
Subject: RE: Assessments for Benchmark proposal

Hi

I hope this email finds you well.

We are trying to finalise our thinking on the licensing implications. We have been asked whether the discharge constitutes 'pollution', in terms of substances in the maritime area which result in harm to living resources and marine ecosystems, or whether the output is sufficiently clean as to not constitute 'pollution' following the treatment of the water in the cleantreat system. In terms of chemical pollution, MS seeks SEPA's advice on this issue before we can conclude our considerations. Benchmark has submitted an 'Overview of the Practical Operation of CleanTreat® in Scotland', sent to SEPA by benchmark on 7th June, which provides some details on the activity and we understand you've also seen the draft ERA during a meeting between yourselves and Benchmark. As requested below, if more is needed for SEPA to be able to consider this, please can you let us know?

We understand that the trial in Norway was granted the necessary permissions to allow it to go ahead on the thinking that the proposal did not constitute pollution.

Can I ask you to consider this aspect and let us know as you soon as possible please?

PDF #19:



30 May 2019

Mr T A'Hearn
SEPA
Strathallan House
Castle Business Park
Stirling
FK9 4TZ

By Email

Dear Terry,

Outwith scope

In this context, you undertook to look again at the potential for trials of novel lice treatment methods and the barriers in the way of Scottish trials for the CleanTreat innovation which the developers believe has no environmental impact at sea. The novel approach has been trialled in Norway successfully and now requires field trials in Scotland. It has the potential to reduce other medicinal treatment methods for lice significantly and reduce environmental impact from farms. We understand that there have been discussions with the company involved though no progress has been made to take forward trials in Scotland. If you required further information on the detail of the issue, we can provide it, though your team have worked with [redacted] at Marine Scotland and the company involved directly already.

Outwith scope

I am copying this letter to Roseanna Cunningham, Cabinet Secretary for Cabinet Secretary for Environment, Climate Change and Land Reform and Fergus Ewing, Cabinet Secretary for the Rural Economy.

I look forward to your early response.

Yours sincerely,

Julie Hesketh-Laird
Chief Executive

c.c. Roseanna.Cunningham.msp@parliament.scot
Fergus.Ewing.msp@parliament.scot

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Use of Ectosan and Clean Treat in the UK- Meeting 2

Meeting Location: 11th April 2019, 3.15-4.00pm, SEPA Offices, Stirling

Attendees:

Benchmark AH	SEPA	MS	VMD

Commented [redacted]: Please could I ask you to add any attendees I have missed as I didn't catch everyone's names, particularly those participating by phone

General Discussion Points

BMK stated our case to move forwards with Clinical trials in Scotland:

- It was explained that [redacted] the CleanTreat[®] system, [redacted]
- [redacted]
- Our preferred route was [redacted]
- BMK indicated a significant investment [redacted] and that this level of investment would only be approved by the BMK board [redacted]
- BMK indicated that we were hoping for field trials for Ectosan in Scotland later this year (2019).

This initiated the discussion around the licenses, those issued by Marine Scotland and those by SEPA. MS Licenses wellboats for their discharges, while SEPA issues CAR (controlled activity regulation) licenses for the farms. MS noted that the granting of the well boat licence includes a public notice.

https://www.sepa.org.uk/media/34761/car_a_practical_guide.pdf

The transport of treatment water [redacted] was raised:

- Marine Scotland looked at the discharge [redacted] This needs to be clarified by the MS legal department.
- [redacted]
 - [redacted]
- [redacted]
- [redacted]

Commented [redacted] could you provide further information on this process?

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- It was agreed that there was a need for further clarity on the subject and that MS and SEPA legal teams would need to be involved in drafting a license to allow CleanTreat® at an approved site
- **Req 10(5)(e)**

There was discussion regarding what other countries are doing and SEPA indicated that they have been talking to Canada and Norway and their interpretation of OSPAR regulations and the London Convention:

<https://www.ospar.org/>

<http://www.imo.org/en/OurWork/Environment/LCLP/Pages/default.aspx>

indicated he would like to discuss with NoMA their approach to the trials already being undertaken in Norway.

In order to move forward, BMK agreed to provide more detailed information on the trial plans, the validation of the CleanTreat®, the validation of the **Req 10(5)(e)** and the draft ERA for Norway.

The issue of the confidentiality of any data/methods provided outside of the official field trial application was discussed. SEPA indicated that all correspondence must be marked commercially sensitive and confidential. If this is the case, they can refuse any freedom of information (FOI) requests based on commercial sensitivity grounds. SEPA regularly refuse FOI requests on this basis.

also stated the VMD would like to review the proposed field trial protocol. Statistical Updates and review will be done by

BMK also indicated they would like to have a further in-depth discussion with SEPA regarding the methodology for the ERA and the modelling required. This would take place in person between SEPA and (BMK environmental expert), with other interested parties participating by telephone.

Actions

1. BMK to provide by mid-May:
 - a. The **Req 10(5)** and method validation
 - b. Information on the validation of the CleanTreat®
 - c. Proposed trial design (outline of the treatments on the site, movement of water, cleaning of the water and discharge)
 - d. The draft ERA for Norway
 - e. Draft field trial protocol
2. SEPA /MS / VMD to outline what we can do in the field trials based on #1.
3. Confidentiality /NDA / FIO They recommended we apply appropriate legal terms Commercially Sensitive etc:

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4. [redacted] to set up the separate discussion on the ERA.
5. SEPA and MS Legal teams to discuss **Req 10(5)(e)** (CAR for discharge location, well boat licence etc), and recommend next steps.

Other points

[redacted] be on extended leave starting July and [redacted] will be our contact and owner of the process during [redacted] absence.

MS indicated that there were plans to have SEPA manage all licensing of wellboats associated with aquaculture farms.

A visit to the CleanTreat® vessel during its operation in Norway was offered to interested parties and accepted. [redacted] to facilitate arrangements.

PDF #21:

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Use of Ectosan and Clean Treat in the UK- Final Meeting Minutes

Meeting: 9th October 2018, 1-3.30pm, BAHL, Bush House, Edinburgh

Initial discussions prior to an ATC application in the UK to test Ectosan under field conditions.

Minutes of the meeting between Benchmark Animal Health Ltd (BAHL), Scottish Environmental Protection Agency (SEPA), Veterinary Medicines Directorate (VMD) and Marine Scotland (MS)

Attendees:

BAHL:

SEPA: [redacted] (present for first hour only)

MS:

VMD:

BAHL provided an overview of Ectosan (active substance imidacloprid), the results of *in vitro* and *in vivo* laboratory studies, and the results of field testing of the product in Norway.

Data on efficacy, safety and residues were shared.

Points made to BAHL regarding the ATC design

- All information on active content of the product should be provided in **Reg 10(5)(e)**
[REDACTED]
- Need to provide a justification for the statistical model to be applied to the UK field trial (no. of fish sampled, no. of cages treated etc)
- Information on the sampling methodology of the fish in the study should be provided and justified to ensure the method provides a representative sampling of each cage **Reg 10(5)(e)**
[REDACTED]
- Protocol should describe how all the sea lice stages are recorded on the treated fish pre and post treatment
- Justification for not including **Reg 10(5)(e)**
[REDACTED]
- What other methods may be in place on the farms to prevent re-infection (lice skirts, cleaner fish etc, proximity to other farms) and does this affect the efficacy results?
- Could a neighbouring farm be used as a control for the study?

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Clean Treat

The CleanTreat purification system was described (although information on the method of purification was not provided).

Action: BAHL to provide information on how the purification system works as part of the data package. This will need to be provided under a confidential agreement between all interested parties.

The levels of active present in the fish as they leave the well boat and subsequently excreted must be considered in order to evaluate the environmental impact (i.e. do sediment studies need to be performed in addition to the water column).

SEPA need to understand if the CleanTreat system leads to breakdown products that may also need to be evaluated. BAHL Reg 10(5)(e) can provide further information in the confidential disclosure discussed above.

Method of quantification: SEPA stated that Reg 10(5)(e) would not be sufficient for validation of specificity and would need to be supported by data from Reg 10(5)(e) to demonstrate that the peak being assessed was specific and not arising from Reg 10(5)(e)

Risk mitigating measures: BAHL need to demonstrate the CleanTreat system is under control in order to be considered as a risk mitigation for the ERA. The capacity of the system and understanding when to stop is an important control measure to prevent accidental discharge.

The worst-case scenarios should be identified, and limits applied to prevent use in these situation (i.e. bad weather). BAHL should seek parallels with other industries where transfer of material between vessels occurs (i.e. the oil and gas industry where materials are transferred between vessels).

Legislative framework: The legal body that would have jurisdiction for the use of CleanTreat is driven by the vessel on which it is placed (e.g. well boat vs platform support vessel (PSV)). If placed on the well boat then discharge would need to be within the vicinity of the farm and Marine Scotland and SEPA may be involved. If it is used on a PSV away from the site, the legislative body is less clear. If a scenario that is analogous to an existing situation (i.e. ship to ship refuelling) can be made, this may assist in the decision making.

Action: BAHL to make a proposal for the ATC trial on how the CleanTreat system would operate. This will be commented on by Marine Scotland and SEPA to advise if further regulatory bodies need to be involved

MS and SEPA suggested that the use of CleanTreat with an already approved medicine (e.g. Salmosan Vet) would be desirable as there are sites with discharge consents and modelled releases and sites already treating with well-boats. A trial could potentially utilise these existing mechanisms, assessments.

BAHL would like to seek clarification on why this is seen as required, as the system has been evaluated most thoroughly for imidacloprid.

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Discussion on the environmental aspects

The available data on the environmental laboratory studies was provided. The applicability of the Water Framework Directive (WFD) was discussed. It was stated that the VMD and SEPA do not use the same methodologies for the assessment of environmental risk. Also the validation of WFD analytical methods usually need to meet ISO17025 to be accepted as an environmental monitoring tool. (e.g. <http://publications.jrc.ec.europa.eu/repository/bitstream/JRC99958/lbna27813enn.pdf>)

Action: SEPA could you please clarify if ISO validation is required for the method applied on the CleanTreat vessel or just for the methods used for environmental monitoring?

Post meeting note: All analysis should meet the principles of GLP/ISO which includes validation and QA/QC although full ISO17025 is not at present required under CAR for fish farm medicines.

SEPA stated that the WFD should be considered in a site-specific ERA and that the WFD methodology allows for data from all water studies published in the public domain of suitable quality to be taken into account (i.e. including freshwater studies if appropriate). The RIVM 2014 review of imidacloprid could be used as a model for developing an assessment under the WFD. This is due to the nature of the active substance that is already on the WFD watch list for environmental protection. Given that a RIVM have undertaken a WFD EQS derivation this should be able to provide an indication of how such an EQS derivation could be undertaken, although it should be noted that this does not constitute an approved environmental standard limit in the UK.

BAHL would appreciate any guidance that can be provided on the application of the WFD and RIVM report into the Ectosan ERA.

The pattern of use of the product should be taken into account; is the discharge considered to be acute (i.e. one-off or infrequent single point discharges on a site) or chronic (i.e. regular discharges over a 12 month period on a site).

The impact of sediment also should be considered if the compound is excreted from the treated fish and subsequently found in the sediment. Laboratory studies to examine how the compound is excreted (in faecal matter or other organic waste), should be performed. If this is not found, sedimentary evaluation in the ERA may not be required. Data gathered in the field may be supportive.

SEPA asked if active substance discharged into the water (after purification) would subsequently bind to organic matter in the water column and become a sedimentary deposit. BAHL would appreciate advice on how to evaluate this in the laboratory or field situation.

Next Actions

BAHL to provide a proposal for;

- The design of the ATC trial in Scotland
 - No. of fish to be treated
 - Statistical justification for the number of fish to be treated and the sampling regime to be applied to provide a statistically robust evaluation of efficacy
- The use of CleanTreat

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- Which vessel will CleanTreat be placed on and where will it be sited relative to the farm?
- MS/SEPA to provide advice on the legislative framework to be applied to the proposed discharge site
- Advice is required from the VMD/SEPA on the correct environmental model that should be used for the site selected.
- Following this, BAHL will run the appropriate model and provide an ERA for the trial

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[PDF #22:](#)

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Use of Ectosan and Clean Treat in the UK

Commented

Insert date and time?

Initial discussions prior to an ATC application in the UK to test Ectosan under field conditions.

Minutes of the meeting between Benchmark Animal Health Ltd (BAHL), Scottish Environmental Protection Agency (SEPA), Veterinary Medicines Directorate (VMD) and Marine Scotland (MS)

Attendees:

BAHL:

SEPA:

MS:

VMD:

BAHL provided an overview of Ectosan (active substance imidacloprid), the results of *in vitro* and *in vivo* laboratory studies, and the results of field testing of the product in Norway.

Data on efficacy, safety and residues were shared.

Points made to BAHL regarding the ATC design

- All information on active content of the product should be provided in Reg 10(5)(e) [redacted].
- Need to provide a justification for the statistical model to be applied to the UK field trial (no. of fish sampled, no. of cages treated etc)
- Information on the sampling methodology of the fish in the study should be provided and justified to ensure the method provides a representative sampling of each cage Reg 10(5)(e) [redacted]
- Protocol should describe how all the sea lice stages are recorded on the treated fish pre and post treatment
- Justification for not including Reg 10(5)(e) [redacted]
[redacted]
[redacted]
- What other methods may be in place on the farms to prevent re-infection (lice skirts, cleaner fish etc, proximity to other farms) and does this affect the efficacy results?
- Could a neighbouring farm be used as a control for the study?

Clean Treat

The CleanTreat purification system was described (although information on the method of purification was not provided).

Action: BAHL to provide information on how the purification system works as part of the data package. This will need to be provided under a confidential agreement between all interested parties.

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The levels of active present in the fish as they leave the well boat and subsequently excreted must be considered in order to evaluate the environmental impact (i.e. do sediment studies need to be performed in addition to the water column).

SEPA need to understand if the CleanTreat system leads to breakdown products that may also need to be evaluated. BAHL Reg 10(5)(e) [redacted] can provide further information in the confidential disclosure discussed above.

Method of quantification: SEPA stated that Reg 10(5)(e) [redacted] would not be sufficient for validation of specificity and would need to be supported by data from Reg 10(5)(e) [redacted] to demonstrate that the peak being assessed was specific and not arising from Reg 10(5)(e) [redacted]

Risk mitigating measures: BAHL need to demonstrate the CleanTreat system is under control in order to be considered as a risk mitigation for the ERA. The capacity of the system and understanding when to stop is an important control measure to prevent accidental discharge.

The worst-case scenarios should be identified, and limits applied to prevent use in these situation (i.e. bad weather). BAHL should seek parallels with other industries where transfer of material between vessels occurs (i.e. the oil and gas industry where materials are transferred between vessels).

Legislative framework: The legal body that would have jurisdiction for the use of CleanTreat is driven by the vessel on which it is placed (e.g. well boat vs platform support vessel (PSV)). If placed on the well boat then discharge would need to be within the vicinity of the farm and Marine Scotland and SEPA may be involved. If it is used on a PSV away from the site, the legislative body is less clear. If a scenario that is analogous to an existing situation (i.e. ship to ship refuelling) can be made, this may assist in the decision making.

Action: BAHL to make a proposal for the ATC trial on how the CleanTreat system would operate. This will be commented on by Marine Scotland and SEPA to advise if further regulatory bodies need to be involved

MS and SEPA suggested that the use of CleanTreat with an already approved medicine (e.g. Salmosan Vet) would be desirable.

BAHL would like to seek clarification on why this is seen as required, as the system has been evaluated most thoroughly for imidacloprid.

Discussion on the environmental aspects

The available data on the environmental laboratory studies was provided. The applicability of the Water Framework Directive (WFD) was discussed. It was stated that the VMD and SEPA do not use the same methodologies for the assessment of environmental risk. Also the validation of WFD analytical methods usually needs to meet ISO17025 to be accepted as an environmental monitoring tool. (e.g. <http://publications.jrc.ec.europa.eu/repository/bitstream/JRC99958/lbna27813enn.pdf>)

Action: SEPA could you please clarify if ISO validation is required for the method applied on the CleanTreat vessel or just for the methods used for environmental monitoring?

SEPA stated that the WFD ~~must-should~~ be considered in ~~the~~ a site specific ERA and that the WFD methodology allows for data from all water studies published in the public domain of suitable quality to ~~should~~ be taken into account (i.e. including freshwater studies if appropriate). The RIVM 2014 review of imidacloprid ~~should-could~~ be used as a model for developing an assessment under the

Commented [2]: I think we said this in terms of these substances are already approved as fish medicines in the UK and there are sites with discharge consents and modelled releases and sites already treating with well-boats. A trial could potentially utilise these existing mechanisms, assessments etc.

Commented [2]: All analysis should meet the principles of GLP/ISO which includes validation and QA/QC although full ISO17025 is not at present required under CAR for fish farm medicines.

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WFD. This is due to the nature of the active substance that is already on the WFD watch list for environmental protection. Given that a RIVM have undertaken a WFD EQS derivation this should be able to provide an indication of how such an EQS derivation could be undertaken although it should be noted Account must be taken on the proposed EQS values stated in RIVM, although it is accepted that this does not constitute an approved environmental standard limit yet in the UK.

BAHL would appreciate any guidance that can be provided on the application of the WFD and RIVM report into the Ectosan ERA.

The pattern of use of the product should be taken into account; is the discharge considered to be acute (i.e. one-off or infrequent single point discharges on a site) or chronic (i.e. regular discharges over a 12 month period on a site).

The impact of sediment also should be considered if the-is-the compound is excreted from the treated fish and subsequently found in the sediment. Laboratory studies to examine how the compound is excreted (in faecal matter or other organic waste), should be performed. If this is not found, sedimentary evaluation in the ERA may not be required. Data gathered in the field may be supportive.

SEPA asked if active substance discharged into the water (despite-toafter purification) would subsequently bind to organic matter in the water column and become a sedimentary deposit. BAHL would appreciate advice on how to evaluate this in the laboratory or field situation.

Next Actions

BAHL to provide a proposal for;

- The design of the ATC trial in Scotland
 - No. of fish to be treated
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 - Following this, BAHL will run the appropriate model and provide an ERA for the trial

PDF #23:

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Use of Ectosan and Clean Treat in the UK

Initial discussions prior to an ATC application in the UK to test Ectosan under field conditions.

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Attendees:

BAHL:

SEPA:

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VMD:

BAHL provided an overview of Ectosan (active substance imidacloprid), the results of *in vitro* and *in vivo* laboratory studies, and the results of field testing of the product in Norway.

Data on efficacy, safety and residues were shared.

Points made to BAHL regarding the ATC design

- All information on active content of the product should be provided in **Reg 10(5)(e)**
- Need to provide a justification for the statistical model to be applied to the UK field trial (no. of fish sampled, no. of cages treated etc)
- Information on the sampling methodology of the fish in the study should be provided and justified to ensure the method provides a representative sampling of each cage **Reg 10(5)(e)**
- Protocol should describe how all the sea lice stages are recorded on the treated fish pre and post treatment
- Justification for not including **Reg 10(5)(e)**
- What other methods may be in place on the farms to prevent re-infection (lice skirts, cleaner fish etc, proximity to other farms) and does this affect the efficacy results?
- Could a neighbouring farm be used as a control for the study?

Clean Treat

The CleanTreat purification system was described (although information on the method of purification was not provided).

Action: BAHL to provide information on how the purification system works as part of the data package. This will need to be provided under a confidential agreement between all interested parties.

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The levels of active present in the fish as they leave the well boat and subsequently excreted must be considered in order to evaluate the environmental impact (i.e. do sediment studies need to be performed in addition to the water column).

SEPA need to understand if the CleanTreat system leads to breakdown products that may also need to be evaluated. BAHL **Req 10(5)(e)** can provide further information in the confidential disclosure discussed above.

Method of quantification: SEPA stated that **Req 10(5)(e)** would not be sufficient for validation of specificity and would need to be supported by data from **Req 10(5)(e)** to demonstrate that the peak being assessed was specific and not arising from **Req 10(5)(e)**

Risk mitigating measures: BAHL need to demonstrate the CleanTreat system is under control in order to be considered as a risk mitigation for the ERA. The capacity of the system and understanding when to stop is an important control measure to prevent accidental discharge.

The worst-case scenarios should be identified, and limits applied to prevent use in these situation (i.e. bad weather). BAHL should seek parallels with other industries where transfer of material between vessels occurs (i.e. the oil and gas industry where materials are transferred between vessels).

Legislative framework: The legal body that would have jurisdiction for the use of CleanTreat is driven by the vessel on which it is placed (e.g. well boat vs platform support vessel (PSV)). If placed on the well boat then discharge would need to be within the vicinity of the farm and Marine Scotland and SEPA may be involved. If it is used on a PSV away from the site, the legislative body is less clear. If a scenario that is analogous to an existing situation (i.e. ship to ship refuelling) can be made, this may assist in the decision making.

Action: BAHL to make a proposal for the ATC trial on how the CleanTreat system would operate. This will be commented on by Marine Scotland and SEPA to advise if further regulatory bodies need to be involved

MS and SEPA suggested that the use of CleanTreat with an already approved medicine (e.g. Salmosan Vet) would be desirable.

BAHL would like to seek clarification on why this is seen as required, as the system has been evaluated most thoroughly for imidacloprid.

Discussion on the environmental aspects

The available data on the environmental laboratory studies was provided. The applicability of the Water Framework Directive (WFD) was discussed. It was stated that the VMD and SEPA do not use the same methodologies for the assessment of environmental risk. Also the validation of WFD analytical methods usually needs to meet ISO17025 to be accepted as an environmental monitoring tool. (e.g. <http://publications.jrc.ec.europa.eu/repository/bitstream/JRC99958/lbna27813enn.pdf>)

Action: SEPA could you please clarify if ISO validation is required for the method applied on the CleanTreat vessel or just for the methods used for environmental monitoring?

SEPA stated that the WFD ~~must~~ should be considered in ~~the~~ a site specific ERA and that the WFD methodology allows for data from all water studies published in the public domain of suitable quality to ~~should~~ be taken into account (i.e. including freshwater studies if appropriate). The RIVM 2014 review of imidacloprid ~~should~~ could be used as a model for developing an assessment under the

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Commenter : All analysis should meet the principles of GLP/ISO which includes validation and QA/QC although full ISO17025 is not at present required under CAR for fish farm medicines.

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[PDF #25:](#)

From: @gov.scot
Sent: 12 September 2019 10:10
To:
Cc: gov.scot; @gov.scot
Subject: RE: benchmark: next steps
Attachments: ATT00003.txt

Dear ,

I have been asked to work with SEPA to provide the background in a brief to Cab Sec and our director has requested that this includes some read across to what happened in Norway, insofar as we know:

- when did they approach Norway,
- how quickly did Norway ok it,
- why any concerns we hold were not of such great import to Norway etc.

From the timelines in a paper submitted to marine Scotland:

A summary of these trials and actions to date is shown below:

- November 2016 permission granted for first field trial of 8m fish/8 farms
- November 2017 first field trial sites completed up to 100% efficacy against lice and no detectable residue of Ectosan® released
- May 2018 Application for Trout field trials submitted
- July 2018 Field trial for trout permission received, 4m fish/4 farms
- May 2018 Application for Field trial re-using water treatment submitted
- May 2018 Several fold increase in CleanTreat efficiency
- July 2018 Field trial with re-use water permission received, 6m fish/6 farms
- July 2018 Atlantic Salmon trials completed
- September 2018 Further optimization of the CleanTreat system to maximize runtime and efficiency
- October 2018 Trout trials completed
- February/March 2019, 2 sets of applications for further field trials in Norway under development

My recollection of benchmark first contact with MS-LOT was in Oct 2018.

From the above timeline it is not clear how long the Norwegian authorities took to determine any application for a trial. Are you aware of how the process went?

What is clear is that field trials were permitted in Norway with a level of discharge that appears to be above the EQS. Could you please provide a narrative for inclusion in the brief around SEPA's concerns with what has been proposed? It would be my intention to provide this information alongside the detail requested below around the list of requirements to try to map out any application process for benchmark.

I have been asked to provide a timeline for the approval process. Obviously this will be dependent on the provision of the right information from benchmark. Marine licence applications usually take 12 weeks to process and so a time line in that regard is simple. However, I really need to get an answer to the OSPAR question and so would really appreciate a response to the 'pollution' question.

From: (MARLAB)
Sent: 11 September 2019 16:10
To: @sepa.org.uk>; @sepa.org.uk>
Cc: (MARLAB) @gov.scot>
Subject: benchmark: next steps

Dear

It seems as though we have some next steps and that we can move forward on a few aspects to help benchmark meet the information requirements for a trial and the level of detail needed to make an application to us.

I understand that, should we advise Benchmark that they could submit a licence application, it would need to be supported by certain evidence, much of which may have been previously discussed but, in terms of documentation to support an application, should be presented by Benchmark in package to support (at this time) a marine licence application.

In order to move this on, please can you respond to my question in relation to whether this constitutes pollution or not? I have attached again for ease of reference. If there are methods by which this can be controlled to such levels as to not constitute pollution, please can you detail these? These may be some of the measures and steps laid out below.

I understand the supporting information should be as follows (can you please advise if I have got this wrong, or have missed anything?):

1. Recognising the **Reg 10(5)(e)** from the Netherlands in freshwater, evidence of how the discharge (or effluent at the edge of the mixing zone) will meet that.
2. Any physical mechanism by which Benchmark could demonstrate meeting the EQS by techniques to enhance dilution to an acceptable level.
3. Details relating to fate and behaviour, in particular persistence in the environment, recognising the receiving environment in Scotland.
4. Evidence to be provided to meet certain European standards – perhaps you could help phrase that?
5. A trial methodology in order to show adequate testing by acceptable methods to ensure that discharge is within acceptable levels.
6. Details of the expected breakdown products
7. a Best Practicable Environmental Option assessment report documenting the consideration of other options for handling.
8. information on the hydrography of the intended discharge location
9. perhaps an assessment of any effects upon other receptors (such as fishing interests, wild fish interests and the features of any designated sites proximal to the proposed location).

I understand that SEPA has already asked Benchmark for some of the above, so please can you advise what has been supplied and how it falls short of the required detail.

Hope this is self-explanatory, please call if not and that you for your help on this to date.

[PDF #26:](#)

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Use of Ectosan and Clean Treat in the UK

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Reg 10(5)

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SEPA need to understand if the CleanTreat system leads to breakdown products that may also need to be evaluated. BAHL Reg 10(5)(e) [redacted] can provide further information in the confidential disclosure discussed above.

Method of quantification: SEPA stated that Reg 10(5)(e) [redacted] would not be sufficient for validation of specificity and would need to be supported by data from Reg 10(5)(e) [redacted] to demonstrate that the peak being assessed was specific and not arising from Reg 10(5)(e) [redacted]

Risk mitigating measures: BAHL need to demonstrate the CleanTreat system is under control in order to be considered as a risk mitigation for the ERA. The capacity of the system and understanding when to stop is an important control measure to prevent accidental discharge.

The worst-case scenarios should be identified, and limits applied to prevent use in these situation (i.e. bad weather). BAHL should seek parallels with other industries where transfer of material between vessels occurs (i.e. the oil and gas industry where materials are transferred between vessels).

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Discussion on the environmental aspects

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[PDF #27:](#)

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Use of Ectosan and Clean Treat in the UK

9th October 2018, Edinburgh

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Data on efficacy, safety and residues were shared.

Reg 10(5)(e)

Points made to BAHL regarding the ATC design

- All information on active content of the product should be provided in **Reg 10(5)(e)** [REDACTED]
- Need to provide a justification for the statistical model to be applied to the UK field trial (no. of fish sampled, no. of cages treated etc). This should include justification for assumptions underlying the sample size calculations and statistical analyses.
- As part of inclusion criteria, justification is required in terms of number of farms, number of pens within farm, and number of fish per pen.
- Information on the sampling methodology of the fish in the study should be provided and justified to ensure the method provides representative sampling of each cage **Reg 10(5)(e)** [REDACTED]
- Protocol should describe how all the sea lice stages are recorded on the treated fish pre and post treatment
- Justification for not including **Reg 10(5)(e)** [REDACTED]
- What other methods may be in place on the farms to prevent re-infection (lice skirts, cleaner fish etc, proximity to other farms) and does this affect the efficacy results? These variables could be considered as part of a statistical modelling approach?

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- Could one or more neighbouring farms be used as positive controls for the study? I.e. comparison to authorised treatments.

Clean Treat

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Action: BAHL to provide information on how the purification system works as part of the data package. This will need to be provided under a confidential agreement between all interested parties.

The levels of active present in the fish as they leave the well boat and subsequently excreted must be considered in order to evaluate the environmental impact (i.e. do sediment studies need to be performed in addition to the water column).

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Action: SEPA could you please clarify if ISO validation is required for the method applied on the CleanTreat vessel or just for the methods used for environmental monitoring?

SEPA stated that the WFD must be considered in the ERA and that data from all water studies published in the public domain should be taken into account (i.e. include freshwater studies). The RIVM 2014 review of imidacloprid should be used as a model for developing an assessment under the WFD. This is due to the nature of the active substance that is already on the watch list for environmental protection. Account must be taken on the proposed EQS values stated in RIVM, although it is accepted that this does not constitute an approved environmental standard limit yet.

BAHL would appreciate any guidance that can be provided on the application of the WFD and RIVM report into the Ectosan ERA.

The pattern of use of the product should be taken into account; is the discharge considered to be acute (i.e. infrequent single point discharges on a site) or chronic (i.e. regular discharges over a 12 month period on a site).

The impact of sediment also should be considered. Is the compound excreted from the treated fish and subsequently found in the sediment. Laboratory studies to examine how the compound is excreted (in faecal matter or other organic waste), should be performed. If this is not found, sedimentary evaluation in the ERA may not be required. Data gathered in the field may be supportive.

SEPA asked if active substance discharged into the water (despite to purification) would subsequently bind to organic matter in the water column and become a sedimentary deposit. BAML would appreciate advice on how to evaluate this in the laboratory or field situation.

Next Actions

BAML to provide a proposal for;

- The design of the ATC trial in Scotland
 - No. of fish to be treated
 - Statistical justification for the number of fish to be treated and the sampling regime to be applied to provide a statistically robust evaluation of efficacy
 - Appropriate control groups and justification.
- The use of CleanTreat
 - Which vessel will CleanTreat be placed on and where will it be sited relative to the farm?
 - MS/SEPA to provide advice on the legislative framework to be applied to the proposed discharge site
 - Advice is required from the VMD/SEPA on the correct environmental model that should be used for the site selected.
 - Following this, BAML will run the appropriate model and provide an ERA for the trial

PDF #28:

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Use of Ectosan and Clean Treat in the UK

9th October 2018, Edinburgh

Initial discussions prior to an ATC application in the UK to test Ectosan under field conditions.

Minutes of the meeting between Benchmark Animal Health Ltd (BAML), Scottish Environmental Protection Agency (SEPA), Veterinary Medicines Directorate (VMD) and Marine Scotland (MS)

Attendees:

BAML:)

SEPA:

MS:

VMD:

BAML provided an overview of Ectosan (active substance imidacloprid), the results of *in vitro* and *in vivo* laboratory studies, and the results of field testing of the product in Norway.

Data on efficacy, safety and residues were shared.

Reg 10(5)(e)

[Redacted text]

Points made to BAHL regarding the ATC design

- All information on active content of the product should be provided in Reg 10(5)(e)
- Need to provide a justification for the statistical model to be applied to the UK field trial (no. of fish sampled, no. of cages treated etc). This should include justification for assumptions underlying the sample size calculations and statistical analyses.
- As part of inclusion criteria, justification is required in terms of number of farms, number of pens within farm, and number of fish per pen.
- Information on the sampling methodology of the fish in the study should be provided and justified to ensure the method provides representative sampling of each cage Reg 10(5)(e)
- Protocol should describe how all the sea lice stages are recorded on the treated fish pre and post treatment
- Justification for not including Reg 10(5)(e)
- What other methods may be in place on the farms to prevent re-infection (lice skirts, cleaner fish etc, proximity to other farms) and does this affect the efficacy results? These variables could be considered as part of a statistical modelling approach?

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- Could one or more neighbouring farms be used as positive controls for the study? I.e. comparison to authorised treatments.

Clean Treat

The CleanTreat purification system was described (although information on the method of purification was not provided).

Action: BAHL to provide information on how the purification system works as part of the data package. This will need to be provided under a confidential agreement between all interested parties.

The levels of active present in the fish as they leave the well boat and subsequently excreted must be considered in order to evaluate the environmental impact (i.e. do sediment studies need to be performed in addition to the water column).

SEPA need to understand if the CleanTreat system leads to breakdown products that may also need to be evaluated. BAHL Reg 10(5)(e) can provide further information in the confidential disclosure discussed above.

Method of quantification: SEPA stated that Reg 10(5)(e) would not be sufficient for validation of specificity and would need to be supported by data from Reg 10(5)(e) to demonstrate that the peak being assessed was specific and not arising from Reg 10(5)(e)

Risk mitigating measures: BAML need to demonstrate the CleanTreat system is under control in order to be considered as a risk mitigation for the ERA. The capacity of the system and understanding when to stop is an important control measure to prevent accidental discharge.

The worst-case scenarios should be identified, and limits applied to prevent use in these situation (i.e. bad weather). BAML should seek parallels with other industries where transfer of material between vessels occurs (i.e. the oil and gas industry where materials are transferred between vessels).

Legislative framework:

Notes from Marine Scotland: *Currently, a marine licence is needed for the deposit of substances or objects from a vessel. This has been the case for several years and to-date MS-LOT has issued many marine licences for the discharge of chemotheraputant from a wellboat. The uncertainty described during the call has come about from a recommendation (QW4 - Integrate wellboat Marine Licence into the CAR Licence) in the Independent review of Scottish aquaculture consenting found at <https://www.gov.scot/publications/independent-review-scottish-aquaculture-consenting/pages/7/>. Adoption of this recommendation, which all parties have signed up to, would lead to wellboat discharges out to 3 nautical miles being permitted under the Controlled Activity Regulations by SEPA. The enabling work has not yet begun on this and so a marine licence would be required. However, MS-LOT understands that the implementation of the recommendation is being pursued. Irrespective of the legislative pathway, SEPA is a statutory consultee to the marine licensing process and their advice should be sought and complied with, in order to inform any application for a marine licence.*

In determining licence applications for the deposit of substances or objects in the seas around Scotland, MS-LOT must consider other options for disposal. You described your CleanTreat system as Reg 10(5)(e) In order to consider any application for discharge, all other options of safe disposal must be considered, including

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consideration of putting residues or effluent water ashore., unless the discharge water is guaranteed to be free of treatment chemicals.

Action: BAML to make a proposal for the ATC trial on how the CleanTreat system would operate. This will be commented on by Marine Scotland and SEPA to advise if further regulatory bodies need to be involved

MS and SEPA suggested that the use of CleanTreat with an already approved medicine (e.g. Salmosan Vet) would be desirable.

BAML would like to seek clarification on why this is seen as required, as the system has been evaluated most thoroughly for imidacloprid.

Post meeting comment from Marine Scotland: *MS (and we understand from the conference call, SEPA) consider it beneficial to see the efficacy of the CleanTreat system in action and advised that, to do this now, in Scotland, under the current consents would be possible. To do this with Ectosan will require further assessment and permissions (currently marine licence where from vessel).*

Future consideration of the efficacy of CleanTreat will be paramount in considerations about permitting discharges.

Discussion on the environmental aspects

The available data on the environmental laboratory studies was provided. The applicability of the Water Framework Directive (WFD) was discussed. It was stated that the VMD and SEPA do not use the same methodologies for the assessment of environmental risk. Also the validation of analytical methods needs to meet ISO17025 to be accepted as an environmental monitoring tool.

Action: SEPA could you please clarify if ISO validation is required for the method applied on the CleanTreat vessel or just for the methods used for environmental monitoring?

SEPA stated that the WFD must be considered in the ERA and that data from all water studies published in the public domain should be taken into account (i.e. include freshwater studies). The RIVM 2014 review of imidacloprid should be used as a model for developing an assessment under the WFD. This is due to the nature of the active substance that is already on the watch list for environmental protection. Account must be taken on the proposed EQS values stated in RIVM, although it is accepted that this does not constitute an approved environmental standard limit yet.

BAHL would appreciate any guidance that can be provided on the application of the WFD and RIVM report into the Ectosan ERA.

The pattern of use of the product should be taken into account; is the discharge considered to be acute (i.e. infrequent single point discharges on a site) or chronic (i.e. regular discharges over a 12 month period on a site).

The impact of sediment also should be considered. Is the compound excreted from the treated fish and subsequently found in the sediment. Laboratory studies to examine how the compound is excreted (in faecal matter or other organic waste), should be performed. If this is not found, sedimentary evaluation in the ERA may not be required. Data gathered in the field may be supportive.

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Post meeting comment from Marine Scotland: *Demonstration of this aspect – coupled with evidence of the amount of therapeutant in proposed discharge will be key considerations for any application to allow discharge to sea.*

SEPA asked if active substance discharged into the water (despite to purification) would subsequently bind to organic matter in the water column and become a sedimentary deposit. BAHL would appreciate advice on how to evaluate this in the laboratory or field situation.

Next Actions

BAHL to provide a proposal for;

- The design of the ATC trial in Scotland
 - No. of fish to be treated
 - Statistical justification for the number of fish to be treated and the sampling regime to be applied to provide a statistically robust evaluation of efficacy
 - Appropriate control groups and justification.
- The use of CleanTreat
 - Which vessel will CleanTreat be placed on and where will it be sited relative to the farm?
 - MS/SEPA to provide advice on the legislative framework to be applied to the proposed discharge site once further information has been received from Benchmark
 - Advice is required from the VMD/SEPA on the correct environmental model that should be used for the site selected.
 - Following this, BAHL will run the appropriate model and provide an ERA for the trial

PDF #29:

From: | [@gov.scot](mailto:) [@gov.scot](mailto:)
Sent: 12 September 2019 16:12
T bmkanimalhealth.com; sepa.org.uk; @gov.scot;
@vmd.defra.gsi.gov.uk; | SEPA.org.uk
Cc: bmkanimalhealth.com; bmkanimalhealth.com;
@bmkanimalhealth.com; bmkanimalhealth.com; @gov.scot;
@gov.scot; @sepa.org.uk
Subject: RE: Commercially Sensitive and Confidential: White paper on use of Clean Treat in field trials in Scotland - meeting

Dear

Thanks for this, and for our discussion just now, it is helping with our consideration which we hope to finalise very soon.

As we briefly discussed, it would be good to sit down with MS (me, and possible and I copied) SEPA and copied) and the VMD copied) to map out the regulatory landscape for you, the information

which is required by our advisers and look to understand the timelines involved and you have agreed that we could meet next week at your office in Edinburgh Friday (20th) at 9.00.

You asked the sort of information that we would be seeking. In terms of next steps it would be good to discuss how we can move forward on a few aspects to help you meet the information requirements for a trial and the level of detail needed to make an application to us. As we discussed, it is our current understanding that it should be possible to process a licence application if the discharge from your proposal does not constitute pollution. To that end there is a level of detail required in submissions to be made, either as pre-app or perhaps as part of a marine licence application. Such information can be discussed at the meeting but below is an outline overview of the requirements:

1. Recognising the **Reg 10(5)(e)** from the Netherlands in freshwater, evidence of how the discharge will meet that or any other suitable evidence for meeting acceptable EQS (you mentioned that you had some aspects to discuss on this)
2. Any physical mechanism by which you can demonstrate meeting an EQS by process or techniques to ensure discharge is within an acceptable level.
3. Details relating to fate and behaviour, in particular persistence in the environment, recognising the receiving environment in Scotland.
4. Evidence to be provided to meet certain European standards and SEPA may be able to advise further on that.
5. A trial methodology in order to show adequate processes and testing by acceptable methods to ensure that discharge is within acceptable levels.
6. Details of any expected breakdown products and toxicity.
7. any future application would need a Best Practicable Environmental Option assessment report documenting the consideration of other options for handling.
8. information on the hydrography of an intended discharge location
9. some consideration of any effects upon other receptors (such as fishing interests, wild fish interests and the features of any designated sites proximal to a proposed location).

I hope this is self-explanatory but please feel free to call and discuss if you wish.

From: @bmkanimalhealth.com>
Sent: 22 August 2019 09:21
T (MARLAB) @gov.scot>; sepa.org.uk;
(MARLAB) gov.scot> @vmd.defra.gsi.gov.u @SEPA.org.uk
Cc: @bmkanimalhealth.com>; @bmkanimalhealth.com>;
@bmkanimalhealth.com>; @gov.scot>;
@gov.scot>

Subject: RE: Commercially Sensitive and Confidential: White paper on use of Clean Treat in field trials in Scotland

Dear

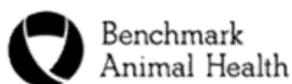
Please find attached the response to the questions Marine Scotland raised on the white paper. It hopefully answers the question you have. If not, please don't hesitate to call me.

The key for us to move forward is how the current or pending regulatory framework influences our proposals for discharges at sea. Our preference is to be able to **Reg 10(5)(e)**

Reg 10(5)(e)

we need to know what is possible within the regulatory framework around the discharge.

Animal Health Division



Bush House, Edinburgh Technopole, Edinburgh, EH26 0BB

From: [@gov.scot](mailto:) <[@gov.scot](mailto:)>
Sent: 21 August 2019 14:48
To: [@bmkanimalhealth.com](mailto:)>; [@sepa.org.uk](mailto:); [@gov.scot](mailto:);
[vmd.defra.gsi.gov.uk](mailto:); | [SEPA.org.uk](mailto:)
C [@bmkanimalhealth.com](mailto:)>;
[bmkanimalhealth.com](mailto:)>; [@bmkanimalhealth.com](mailto:)>;
[@bmkanimalhealth.com](mailto:)>; [@gov.scot](mailto:); [@gov.scot](mailto:)
Subject: RE: Commercially Sensitive and Confidential: White paper on use of Clean Treat in field trials in Scotland

Dear

I hope this finds you well and you had a good summer holiday.

I note that you haven't responded to the below query, we are obviously trying to provide you with an answer to the licensing question and I was after the below info to try to help that. It's the third question below in relation to where and under what circumstance the boat discharging the effluent water is proposed to carry out that activity which is key and I had imagined that might be a fairly simple question to answer.

Perhaps you could give me a call if providing the below is proving problematic?

(MARLAB)
Sent: 02 July 2019 16:19
T [@sepa.org.uk](mailto:)>;
(MARLAB) <| [@gov.scot](mailto:)>; [@vmd.defra.gsi.gov.uk](mailto:)>;
[@SEPA.org.uk](mailto:)>
[@bmkanimalhealth.com](mailto:)>;
[@bmkanimalhealth.com](mailto:)>; [@bmkanimalhealth.com](mailto:)>;
[@bmkanimalhealth.com](mailto:)>; [@gov.scot](mailto:)>;
[@gov.scot](mailto:)>

Subject: RE: Commercially Sensitive and Confidential: White paper on use of Clean Treat in field trials in Scotland

Dear I

Thank you for the documentation submitted.

As you know, there are some regulatory questions to close off, in addition to the ongoing technical discussion. At the meeting at SEPA's office you proposed the submitted 'white paper' to provide the detail on the discharge to sea to enable MS to consider the regulatory pathway, whilst the technical discussion proceeded between Benchmark and SEPA, as the statutory consultee to the marine licensing process.

The consideration of the regulatory questions is ongoing. However, the application of marine licensing rules to your proposal is in relation to the actual discharge to sea. Your 'white paper' doesn't seem to provide sufficient detail on how that would happen, the interaction of the vessels, the transfer of effluent water and how and where the cleantreat vessel would undertake any discharge activity, for us to come to a view. I'm not able to find the required level of detail in the paper submitted to us by Benchmark titled 'Benchmark Animal Health Limited Ectosan® & Cleantreat, Effective Sea Lice Treatment with Proven Prevention of Environmental Impact, for Field Trials in Scotland' either.

As I have asked before, what we really need to know for our consideration of the regulatory questions is:

What is being discharged to sea?

Where is this taking place?

What is the pathway of the effluent water **Reg 10(5)(e)**

If you had any information in relation to how your trial was permitted in Norway.

I am aware that we are approaching the holiday period and I am on leave from Thursday, I therefore ask that you please copy my colleagues (all copied) into any further correspondence.

From: [@bmkanimalhealth.com](mailto:bmkanimalhealth.com)>
Sent: 07 June 2019 15:48
To: (MARLAB) @sepa.org.uk; (MARLAB) <@gov.scot>; @vmd.defra.gsi.gov.uk>;
(MARLAB) @gov.scot>;
@SEPA.org.uk>
Cc: @bmkanimalhealth.com>; @bmkanimalhealth.com>;
@bmkanimalhealth.com>; @bmkanimalhealth.com>
Subject: Commercially Sensitive and Confidential: White paper on use of Clean Treat in field trials in Scotland

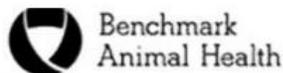
Dear Everyone,

Please find attached the white paper on how we would like to use our CleanTreat vessel during the field trials for Ectosan in Scotland. This paper includes information on the **Reg 10(5)(e)** and its validation. Also attached is the draft protocol for the trial we wish to perform. The draft ERA has already been shared with SEPA by and discussed in a face to face meeting.

Following your review of the attached information it would be great to get your feedback as soon as possible so we can build a roadmap to the field trial application and commencement of trials in 2019. If you need any further information please don't hesitate to contact me and we would be happy to meet to discuss this at your earliest convenience.

Kind Regards

Animal Health Division



Bush House, Edinburgh Technopole, Edinburgh, EH26 0BB

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