CONFIDENTIAL

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 (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.

Reg 10(5)(e) [redacted]

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?

- Could one or moreneighbouring farms be used as positive contros 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: 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:

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*

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

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.

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.

Post meeting comment from Marine Scotland: *Demonstration of this aspect – coupled with evidence of the amount of theraputant 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