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.

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.

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.

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

- 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