Benchmark®
Animal Health

Benchmark Animal Health Norway AS
Bradbenken 1
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Norway

31 March 2021

**Ref. Feedback to consultation regarding proposal for regulatory changes in the aquaculture regulations "HØRINGSNOTAT» with a deadline 31 March 2021**

Benchmark (BMK) thanks the regulators for the opportunity to provide input to the consultation memorandum and the proposed regulatory changes in the Aquaculture regulations**.** Our input is limited to the proposed changes to requirements for the use and release of medicines (Chapter 7 in the consultation note "Draft of amendment to requirements concerning the use and discharge of medicinal product").

We recommend that the aquaculture regulations and the production area regulations, which are also under consultation, should be seen in context together as there appear to be overlapping areas between these regulations.

We are in favor of extending the regulations to apply to all medicinal treatments. We also find it positive that the proposal includes discharges of treatment water in the aquaculture regulations and that requirements are to be set for risk assessments and reporting of such discharges. The proposed legislation may thus give a dynamic and at all times, up to date risk assessment for the environmental impact of a pharmaceutical treatment. We therefore overall support the repeal of §§ 15a and 15b and the introduction of a function-based regulation, however clear guidance for the user is required for this framework in order to be effective.

BMK believes that necessary measures must be based on available knowledge of the properties of each individual medicine. Is important to bear in mind that to use a veterinary medicinal product (MVP) a marketing authorisation must be approved in accordance with Article 12(3) in EU Directive 2001/82/EC as amended by a competent authority. For this purpose, an application dossier containing all the required documentation which respect to quality (manufacture and packaging of the product), safety (human food safety (including withdrawal periods), user safety and the environment and the safety and efficacy of the MVP in the target species should be assessed. Only when all these criteria are addressed, and a positive benefit/risk evaluation is made will a competent authority grant a marketing authorisation for a new VMP.

There is no reference in the consultation memorandum to the approved marketing authorisation and the information that is held by the Norwegian Medicines Agency (SLV). Therefore, we find it critical that the comprehensive environmental documentation provided to SLV is considered by the Directorate of Fisheries when preparing guidelines for risk assessments.

It is important that such documentation is treated with confidentiality and is linked to the registered product and not to the generic active substance. Generic medicines are required to produce their own environmental risk assessments as part of their registration and therefore information may differ.

The consultation memorandum also contains a section on purification of treatment water with added medicine. We would strongly support this, but it should be noted that technologies should be risk assessed according to their specifications. Benchmark will soon be launching our new water purification system CleanTreat®, please contact us for further information.

Purification systems may not necessarily be located onboard wellboats and therefore the conditions of discharge applied to wellboats may not be appropriate in all cases. Considering purification systems will significantly reduce medicine released into the environment and undergo rigorous environmental risk assessment to show a stationary discharge does not pose any risk, it is proposed an allowance for stationary discharge is added to the legislation at this time.

Considering that such technology will be available for the Norwegian industry in only few months, we would like to request that permanent exceptions for the risk assessment for such technologies with a satisfactory degree of purification like CleanTreat® are considered.

**Comments on specific sections:**

We would like to clarify that BMK product Salmosan® Vet is a licensed product in Norway and marketing authorization details can be found in the following webpage of SLV:

https://www.legemiddelsok.no/sider/Legemiddelvisning.aspx?pakningId=8bdf0c3c-e12f-47c7-85be-5c60604a8762&f=Han;Mar;par;gen&searchquery=Salmosan+Vet

Therefore, we kindly request that following wording related to Azamethiphos in page 30 should be amended accordingly when referring to Salmosan® Vet including approved text in section 5.3 Environmental properties in current SPC (specified below):

**Current text in the consultation document:**

*Legemidler som tilsettes i badebehandlingsvann*

*Azametifos hører til gruppen av kjemiske forbindelser som kalles organofosfatene, og selges i Norge under navnet Azasure Vet[19] (tidligere solgt under handelsnavnet Salmosan vet). Organofosfater har en hemmende virkning på enzymet acetylkolinesterase. Hemming av dette enzymet fører først til overstimulering av musklene, etterfulgt av blokkering som gir lammelse og død. Krepsdyr er de mest sensitive artene for azametifos. Bløtdyr, pigghuder og fisk ser ut til å være mindre sensitive. Av testorganismer som er anvendt, er det amerikansk hummer som er mest sensitiv. Strandreker og pungreker viser ingen dødelighet etter én times eksponering. Det er heller ikke vist noen effekt på kopepoder.*

*I et forsøk ble det vist at etter behandling med azametifos, kan ikke azametifos detekteres dypere enn 10 meter og fortynningen skjer raskt. Azametifos brytes ned i vann ved hydrolyse med en halveringstid på 8-9 dager.*

*Havforskningsinstituttets Risikorapport 2019 konkluderer med at risiko for effekter på non-target arter vurderes som nær ønsket tilstand basert på moderat kunnskapsgrunnlag. Det er behov for mer kunnskap knyttet til effekter av azametifos på non-target arter, spesielt knyttet til spredning og fortynning og artenes følsomhet for medikamentet.*

**Salmosan Vet information in current SPC;**

5.3 Environmental properties

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Azamethiphos is highly soluble in water (>1g/l) with a low octanol/water partition coefficient (log Kow) of 1.0 g/ml. These characteristics indicate that azamethiphos will remain in the aqueous phase and will not enter the sediments. Azamethiphos has a moderate propensity to adsorb to suspended organic matter; however it is unstable in salt water, degrading with a half-life of <5.6 days (at 12°C), producing non-toxic transformation products. Hydrolytic degradation is the primary breakdown route but photolysis and microbial action will also hasten the process.

Finally, we would like to confirm that BMK strongly believe in the sustainable growth of the salmon industry and with the responsibility that we all have in making this possible.

With Kind Regards,

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