Environment, Climate Change and Land Reform Committee

Environmental impacts of salmon farming

Written submission from PHARMAQ Ltd

We write to offer comment on the Review of the Environmental Impacts of Salmon Farming in Scotland. We do so from the view point of a Marketing Authorisation holder of several veterinary medicinal products (VMPs) that are used in the salmon farming sector. We have restricted our comments to Section 4 of the report, which addresses the effect of the discharge of medicines and chemicals from salmon farming.

Our first comment is that the term 'chemical' is used throughout Section 4 of the report in an inconsistent and confusing manner, with the term chemical used to cover everything from dietary trace metals and anti-foulants, through to pharmaceutical VMPs. The distinction between a pharmaceutical VMP and a chemical is not clear in the report, nor reflective of the major differences in legislation that regulates the registration, manufacture and use of VMPs. We recommend that VMPs and chemicals are discussed in separate sections of the report and that the term chemical is replaced with pharmaceutical in any reference to VMPs.

Section 4.5.1 (p71). We propose the following as a clearer explanation of PNEC:

The PNEC is derived by dividing the obtained laboratory values (LOEC of NOEC) by safety factors of 10, 100 or 1000. A safety factor of 1000 is considered the most protective and results in the most conservative PNEC. A safety factor of 1000 is applied when only a limited amount of data for the species and compound is available and can be reduced when more data becomes available.

Section 4.5.3. refers to "bath treatment chemical plumes extending for up to 8 Km", which appears to be based upon one active pharmaceutical ingredient (API) in one study. The report should acknowledge that environmental dispersion and detection will vary greatly between different classes of API and be balanced by other reports (e.g. Burridge et al. 2010 p. 12) that found API from sea lice treatments to rarely by detected in water beyond 100 m from the cage.

Section 4.6.1. discusses the effects of anti-lice compounds on ecosystems, but fails to cite the European Medicines Agency (EMA) Guideline on the assessment of compounds that are considered to be persistent, bioaccumulative and toxic (PBT), or very persistent and very bio-accumulative (vPvB) substances in veterinary medicinal products. This is the most recent and relevant regulatory guidance relating to the PBT/vPvB assessment of VMPs. This guideline states that VMPs are considered to be persistent or very persistent in marine sediment when the degradation half-life is higher than 180 days at 9°C.

http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2015/09/WC500193826.pdf

4.12. Prognosis and Mitigation. The report includes no reference to purification systems as a mitigation measure for reducing environmental impact of sea lice treatments. Purification systems are a recent innovation that treat the water in which sea lice treatments have been administered before it is discharged, thus eliminating or greatly reducing the environmental input of the active ingredients e.g. http://www.seafoodinnovation.no/article/244/CLEANTREAT_INNOVATIVE_LAUNCH_FROM_BENCHMARK_HOLDINGS.

Such systems also hold great potential to improve the availability of a wider range of VMPs to combat sea lice. The report should acknowledge the potential that purification systems hold in enabling a wider array of VMPs to be made available, whilst minimising/eliminating any potential threat that they may pose to the environment. We strongly advocate that parliament encourages its relevant agencies to be supportive and proactive in the further development and implementation of such innovations.

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