Scottish Salmon
PRODUCERS ORGANISATION

Lin Bunten
SEPA
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Edinburgh
EH12 7AT

9th October 2017

Dear Ms Bunten

COMPLAINTS HANDLING PROCEDURE – STAGE 2 INVESTIGATION – RESPONSE

Thank you for your letter of 28th September responding to mine of 14th July.

Overall, our impression of your investigation of our complaint is that this has been based on information obtained almost entirely from the SEPA staff, whose activities are at the heart of the complaint; and that you have approached this from the point of view of defending SEPA against what SEPA considers to be largely unjustified concerns. However, it is our view that, if the facts behind our complaint are taken together, the picture painted is a different one to that which has emerged from a point by point analysis.

We make the following observations:

P2 i): You summarise the history behind SARF 098. You do not detail the background to the commissioning of this project. Conversations with senior SEPA personnel clearly indicate that before the commissioning of SARF 098 SEPA had scientific evidence to support its concerns that Slice use was having an actual biological impact on all benthic communities (specifically, on crustaceans within the infauna) in the vicinity of fish farms yet, despite assurances that this evidence would be published, none has ever appeared. The SARF report is now being cited as the sole evidence justifying SEPA's actions to reduce or prevent Slice use, yet the consensus amongst those concerned in its production and review is that the report does not provide sufficient evidence to justify such action. Reference to the ASMG minute in P1 ii) reinforces the fact that SARF 098 is at the heart of SEPA's actions on Slice. All of the component parts of the SARF 098 report recommend more research.

P2 ii) The meeting between SEPA officials and MSDAH took place before SARF 098 had been published. SARF operates in strict accordance with the principle that documentation relating to projects has no formal status until final project reports have been reviewed, approved by the Board of SARF and published. Documentation that formed the basis for discussion between SEPA officials and MSDAH was unreviewed and in draft form in October 2015, with the final report being published in May the following year. The fact that MSDAH has been provided with draft documentation to allow them to commission independent expert reviewers is immaterial in relation to this important breach of principle by SEPA officials, one of whom was a Director of SARF at the time the meeting took place.

P2 iii) This refers to a consideration by SEPA's AMT of a paper seeking approval for a course of action to effect a managed phase-out of the use and discharge of SLICE on Scotland's MCFFs'. Although the AMT did not approve the recommendations as they stood, members agreed with the direction contained within the report. In our view, this strongly reinforces the

sense of there being a long standing agenda to remove Slice from use, even when the sole basis for this was the SARF 098 report which stressed the need for further research.

We would be grateful if you would provide us with a copy of the paper referred to in iii) please, along with the minute of the meeting at which it was considered. Please take this as a request under FoI/EIR.

P2 v) We note that a recommendation to commission a review of the EQS for emamectin benzoate was agreed in June 2016. We believe that the review commenced in August 2016, within a very short space of time of endorsement of the recommendation. This implies a considerable degree of urgency having been attached to the review. It is our own experience that the job of scoping and commissioning such a complex review can take a considerable length of time. Can you please confirm that work had not commenced on scoping the review before approval was given in June 2016 by the 'SEPA internal group'.

P3 1.: Overarching complaint - Your analysis indicates that you are given to understand that the course of action followed by SEPA only began once the draft SARF 098 report became available. We wonder which draft triggered this; and does this mean that all three component parts of the SARF098 suite? Part C of the SARF 098 report ('The association between emamectin benzoate use and crustacean assemblages around Scottish fish farms') was only published in early February of this year. This clearly states that *"These results are based on the analysis of observational data";* and recommends that *"further research is required to establish any causal relationship between EMB sedimentary concentration and crustacean assemblage change. This research should be based on manipulative studies where the actual concentration of EMB is controlled, and measured, alongside measurements on the crustacean community".*

Reiterating, SARF operates in strict accordance with the principle that documentation relating to projects has no formal status until final project reports have been reviewed, approved by the Board of SARF and published. In commissioning the PAMP-2 study / SARF 098 through SARF, SEPA (including its Director appointed to the SARF Board) accepted this principle, yet your letter clearly confirms that SEPA acted in advance of the conclusion of the process it had signed up to, including meeting with stakeholders to discuss elements of the draft report, and initiating regulatory action. We are also aware that SEPA engaged with the Veterinary Medicines Directorate to draw the work to their attention. As a consequence, we are advised that VMD made repeated attempts to obtain a copy of the draft report, although requests were rejected citing the principle outlined above. As you know, it is within SEPA's power to prevent Slice being used on fish farm sites by amending CAR licenses and, having taken the appropriate steps, this would be the normal course of action if concerns were as substantial as have been made out. Instead, SEPA i) approached MSD to ask them to voluntarily remove Slice from the market (as they had done previously with Calicide), and discussed an unreviewed, unpublished study with VMD to alert them to an aspect which could potentially have led VMD to suspend the Marketing Authorisation for Slice. As the holder of the Marketing Authorisation for Slice, MSD have a legal duty under pharmacovigilance conditions to make VMD aware of any issues which may affect the Marketing Authorisation, and we understand that this was done.

In following the course of action it has, we believe that SEPA has extracted elements of the work which suited its agenda to remove Slice, while ignoring elements which did not support that agenda.

You find no evidence to suggest that a review of the EQS was identified as a proposed action before the draft SARF098 was available, and have suggested that it is entirely appropriate for the EQS to be reviewed after the length of time Slice has been in use. We do not disagree that periodic reviews of EQSs are in order. However, we would question why the review of the EQS for emamectin benzoate has been linked so closely to the SARF098 report when this could have been carried out at any time, especially in light of intermittent expression of concern by SEPA about the occasional presence of sediment residue levels of emamectin benzoate above near field and far field EQSs, despite there being no linkage with crustacean infauna.

You conclude that there is no evidence of a pre-existing agenda before the publication of the draft (*sic*) report. Parts A & B of the SARF 098 report, including the contextual elements which form an integral part of the report, were published in August 2016 , with Part C being published in February 2017, yet SEPA had clearly embarked on a course of action on Slice before that time. We believe you may have reached a different conclusion had you been aware of information from sources other than within SEPA.

P4: 2. The principle of peer review before publication - You conclude that there was no need to independently review the WRc document before SEPA published it because defined guidance on EQS derivation had been followed. We are not critical of WRc, believing as we do that they have had no option but to follow prescribed guidance. We do not, however, accept that following approved guidance alone is satisfactory. Where there is are major gaps in scientific data it is entirely possible to follow approved guidance, yet still reach a conclusion which will attract justifiable criticism. Peer review prior to publication would have minimised or even obviated the risk of such criticism, yet SEPA chose not to do this, even when the principle of peer review before publication was an inherent element of the publication on which SEPA has founded its current regulatory action on Slice.

We have made SEPA aware of our concerns about the EQS review and its conclusion, and have proposed a way of dealing with the shortcomings of the review.

P4 3.: Need for a comprehensive and scientifically objective study - We have made a proposal to SEPA to carry out the work necessary to gather relevant data to properly populate the EQS review. We remain confident that an independent third-party expert review of the WRc document prior to its publication would have highlighted the major problem of availability of relevant data for EQS derivation.

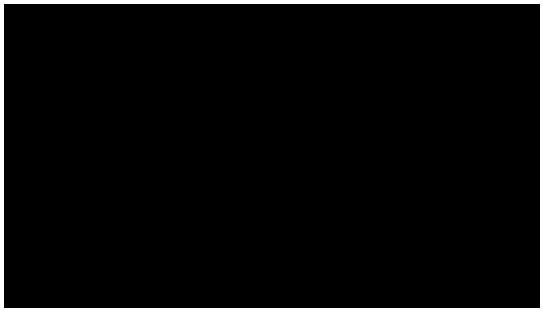
P5 4.: SEPA officials attempting to persuade MSD to remove Slice from the market – That SEPA officials asked MSD to remove Slice from the market is clearly beyond dispute. We feel you have misunderstood our complaint, which is not that the request to remove Slice was based on legal powers, although we did question if such powers exist, it is that officials attempted to persuade MSD to remove Slice when SEPA already has legal powers to prevent Slice being used through the amendment of CAR licenses. The approach adopted by SEPA conveys a strong impression of subterfuge, attempting to pass responsibility for dealing with a problem perceived by them instead of doing this through exercising powers it does have.

SEPA officials have already successfully used this same approach to remove another fully licensed veterinary medicine from the market, an approach which has also attracted serious criticism.

This further reinforces our point that, taken in isolation, the facts as perceived by SEPA may not strongly indicate an ongoing agenda. However, taken together, this paints a compelling picture of linked events consistent with the existence of such an agenda.

P6 5.: Timescale for responses – We appreciate the extension of the deadline for submission of responses on the WRc report and on SEPA's DZR consultation. Our responses were submitted before the 30th September deadline.

Yours sincerely



SCOTT LANDSBURGH
Chief Executive