Dear Clark,

Thank you for your letter of 12 July 2021 advising of a request for further information in relation to Application APP204199.

In light of the recent precedent set by other modified reassessments, we consider that some of the additional information that has been requested by the EPA is unnecessary. We explain the reasoning below and strongly encourage the EPA to reconsider what information they are seeking at this early stage.

Section 63A of the Act allows for applications to be made that only involve specific aspects of the approval(s) for which reassessment is sought. Such applications are referred to as Modified Reassessments. The two most recent completed reassessments according to the EPA's HSNO application register happen to both be modified reassessments. These are APP204060 – which sought to reassess substances identified in the Chemical Review 2019 – 2020, and APP203921, which sought to reassess Benzyl alkonium chlorides (BACs). These applications were considered under section 63A of the Act as modified reassessments and we have deliberately structured our application so that it clearly fits within the scope of this same reassessment regime under this same section of the Act.

Your first question requests that "a review of any new information relating to adverse effects" is provided and states that "part of the evaluation process is to compare the risks and benefits of the affected substances". We note however that this appears to have not been the case for either APP204060 or APP203921, with no assessment of the benefits of any of the substances in these applications being included in the EPA's application form in either instance.

This section of the Act allows for reassessments that involve only a specific aspect of the affected approvals, as opposed to a complete re-evaluation of all the risks, costs and benefits of the use of the approved substances. The EPA's own applications support this contention as they included no assessment of the benefits of the use of the affected approvals in APP204060 or APP203921. We would like to highlight however that the "new" (January 2020) reassessment application form does ask for an assessment of the effect of the proposed change(s) to controls of affected approvals. APP204060 includes this on page 51. However, it is important to note that an assessment of the effects of the reassessment, and a complete review of the effects of using a substance are different things and the latter is not asked for on the application form. Just like APP204060, our application describes the expected effects of the reassessment, both positive and adverse (see page 15). Our application provides at least as much information in this regard as the EPA's own recent modified reassessments. We therefore question why this reassessment request is being asked to provide information that differs from information provided in applications APP204060 and APP203921, applications that were made under the same section of the Act that we intend this application to be assessed under? We consider that this is not necessary given the requested scope of our reassessment.

Coming back to your first question, specifically in relation to international regulatory changes. In APP201045, the reassessment of the approvals in our application which resulted in the current timeframes being set, there was a table in Appendix B of the

application form which outlined on-label uses for each active by the US EPA, PMRA, EU and APVMA. We are happy to provide the EPA with an updated version of this.

In response to your second question, we have no opposition to the EPA making an application of their own accord to apply whatever outcome arises from our application to the other approvals for these actives which we have not requested be reassessed. However we have chosen not to do so as a result of the precedent set in the EPA's reassessment of paraquat. In that decision the EPA was of the opinion that unused approvals had no benefits associated with them but did carry an inherent risk. Whilst some of the groups involved in this application disagreed about these approvals posing such a risk, we have drafted our application to be consistent with this stance taken by the EPA.

Furthermore, none of the manufacturers of currently registered products have indicated a need to reformulate such that they might end up needing to use one of the other approvals not included in this reassessment, so we do not consider that the growers represented are likely to be affected by what happens to those approvals.

In relation to your third question, the proportion of registered substances relative to the number of approvals is not that unusual, but more importantly is irrelevant. You have mentioned that this might be an indication that there is decreasing reliance on these products.

We refer you to the grounds for reassessment application for our current reassessment (APP203975). In this we submitted to the decision-making committee confidential information demonstrating a decrease in the quantity of substances manufactured or imported into NZ and highlighted how this demonstrates that the overall risks of these substances has decreased as fewer are now being used. It was acknowledged that some of their benefits have also decreased as for some sectors and some specific control gaps, alternatives have been identified and adopted. The committee:

"*considered that, while the information provided appears to represent a change in volumes, this does not represent a significant change in the context of the previous reassessment decision, as there was an anticipation and an intention by the DMC that, over time, there would be a reduction in the use of the OPCs*"

Based on the DMC response we chose not to discuss this in our application as the committee indicated that they consider it irrelevant.

Your fourth question addresses critical uses. The groups making this application represent only the growers of the crops that regard the uses as critical. We have no opposition to only being able to use these products for critical uses, as it is for these uses precisely that we are seeking the extension of these approvals. We have listed only those critical uses which have no current alternatives or replacements in our application. We cannot speak for growers of other crops but note that there are other on-label uses that are not included in our application. We also understand that there are some label claims which were removed as part of MPIs reassessment of OPCs which occurred following the EPA assessment.

Our application already addresses alternatives and the lack of success in finding them. This is in section 7 and information in the confidential appendices also relates to this.

If it would assist - we can re-do the critical use table in a way that more distinctly separates out which pests are a critical control gap for which particular crops?

Your fifth request relates to further information on the benefits of the three actives in question. We have already outlined the benefits in our application and they remain unchanged for the affected crops that still regard their use as critical. It is evident from the distinct lack of insecticides registered since the 2013 OPC reassessment and the unsuccessful efforts to find alternatives outlined in our application and confidential appendices that alternatives are **not** available and the control gaps we have outlined remain critical. Consequently, the benefits of these active ingredients to the crops making this application are the same as they were during the 2013 reassessment.

Your sixth question relates to Diazinon. A review of Diazinon is appropriate at this point because of the length of time it takes to discover and register a new control option. There is a candidate which has shown some promise (see the confidential appendices) as a replacement for some uses, but not all. However there is no clear path to overcoming the technical difficulties relating to ensuring the active ingredient remains viable in the soil.

As discussed in our application, supply of soon to be withdrawn products usually runs down 2 – 3 seasons before the ban takes effect. So whilst Diazinon remains approved into 2028, it will likely be in short supply from 2025/6 onwards (this is exacerbated currently due to shipping and logistic delays as a result of the global pandemic). A significant factor for our lack of confidence that a replacement for Diazinon will be identified, registered and available for growers to use by this date is the length of time and the increasing difficulty that the NZ regulatory process poses. The EPA is significantly slower at processing applications for both release and containment than they were around the time of the 2013 reassessment. As an example, Movento took about 10 months to be approved whereas Vayego took 2 years. Fontelis took about 8 months whereas Amicus took ~20 months. The changes to the way the EPA assess applications for containment approvals has also had a profound impact on the ability of crop protection companies to conduct research on new insecticide candidates.

The reality is that the regulatory environment for discovering, registering and introducing new crop protection products is slower and more expensive than in 2013 when the DMC decided on the current phaseout timeframes for Diazinon, Fenamiphos and Methamidophos products. We have not focused on this in our application as the purpose of our application is to keep these important tools available to growers until there are replacements available, and not to criticise EPA operational policy.

If the committee chose to extend Diazinon approvals by five years, but fenamiphos and methamidophos by 10 then that would still provide our industries with a greater opportunity to find replacement tools than is currently the case. We would consider this a positive outcome.

Your seventh question relates to pre-application consultation with Māori. Your query suggests that you do not consider the consultation process we have carried out to be adequate. We respectfully disagree. We attach the email and attachments that were sent to Julian Jackson with Dr Matthew Allen copied in on the 21st of December 2020. In it, we specifically explain that we are wanting to undertake pre-application consultation with Te Herenga and that the EPA website mentions this as an appropriate avenue for this. In our correspondence we specifically requested to be informed if this is no longer an appropriate option for pre-application consultation however we received no advice to the contrary. We note that this is still presented as an option for Māori consultation on the EPA website (as at 15 July 2021), and would like to highlight that we included our full application in addition to a summary.

Our application describes how the effect of our application will be that the risks to Māori and their relationship with the environment, flora, fauna and other taonga species, as identified in the 2013 reassessment, will continue for a longer period of time if our application is successful. Given the nature of what we are proposing, particularly because we are not proposing **any change** to how these substances be used, we were under the impression that conducting pre-application consultation through Te Herenga was an appropriate option for engaging with Māori and ensuring that there is an opportunity to provide input to this application before it is lodged.

No response was received from any Te Herenga members during the 2-month period during which we invited questions and feedback. If any response had been received, we would have answered questions and explained in further detail what this reassessment hopes to achieve and why it is necessary. Because there was no response, we submitted the application to the EPA one week to the day after the end of the consultation period.

Two senior EPA staff members involved in this application were asked to let us know if consulting this way was not appropriate, and neither raised any concern or objections. To suggest that the consultation we have undertaken is somehow inadequate when this approach is currently advised on the EPA website, and given that the EPA staff did not direct us otherwise when asked, is unreasonable. We note that in the application documents for APP204060 and APP203921 the EPA make no mention of any pre-application consultation at all being undertaken with Māori in the application process.

As the current phase out period for two of these actives is fast looming (in less than 2 seasons) and time is of the essence we request that if any of the information and responses in this letter are not agreeable to the EPA that we hold an urgent meeting to discuss options and a positive way forward for both growers represented in this application and the EPA. Please also confirm if you would like an update to the approved uses in the US, Canada, EU and Australia for these actives, as well as a differently formatted GAP table.

Kind regards,

Dr Sally Anderson
Vegetable Research and Innovation Board