To: ACVM team: ACVM.Consultation@mpi.govt.nz
Submission: Chemistry and manufacturing information for agricultural chemicals
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Submitted Information
The information supplied is what is available by the submission close off date of 14 August 2020. Further information may be provided in future to inform ACVM.

1. Introduction

1.1 Agcarm thanks ACVM and welcomes the opportunity to provide feedback in response to the draft consultation document titled "Chemistry and manufacturing information for agricultural chemicals".

1.2 Agcarm is grateful to ACVM for allowing an extension to the original deadline that was not able to be met due to the business impacts Covid-19 has had on our members' day to day activities and their ability to respond to public consultations. This is a critical document for Agcarm CropLife members, and it is important to get right and not rush decision-making.

1.3 This submission represents NZ CropLife members of Agcarm which encompasses the vast majority of crop protection registrants and products in NZ.

1.4 Agcarm CropLife registrants are motivated by the fact that this exercise can reform guidance to align with international regulators which would provide substantial benefits to a wide range of people, industries and stakeholders i.e. registrants, ACVM staff, assessors and growers / farmers / end users of these products. The primary sector of NZ is increasingly important for NZ as a whole, especially now as we recover from the impact of Covid-19.

2. NZ's primary sector role in the recovery

2.1 Agcarm is aware that MPI is aligned with the vision and values of the strategy 'Fit for a Better world[1]' recently released by the Primary Sector Council. Agcarm is also aligned with this given our members are key stakeholders that will play a pivotal role in achieving the challenges this strategy sets out to achieve. Agcarm objectives align very well with fit for a better world.

2.2 At the 2020 Agcarm AGM meeting the MPI CEO Ray Smith referenced the document 'Fit for a better world' and acknowledged the need to accelerate the ACVM process whilst managing the risk. MPI's CEO reiterated that MPI is keen to partner with industry on this to enable

[1] https://fitforabetterworld.org.nz/

products to be brought to market faster and more efficiently. MPI's CEO talked about a changed transformational culture due to Covid-19 and enabling the primary industry to flourish. The suggestions made by Agcarm in this submission to align with APVMA enable this and perfectly align with the government's goals.

2.3 It is ingenuity and a new way of thinking by both registrants and ACVM that will enable NZ's much needed regulatory reform in the area of chemistry and manufacturing information requirements.

2.4 MPI is also a key stakeholder in the Horticulture post Covid-19 recovery strategy[2]. In this strategy the removal of regulatory barriers is a key feature and certainty and confidence are pillars. The idea of this industry-led, government-enabled strategy is that industry and government work together to come up with practical, win-win solutions that can be implemented.

2.5 If Agcarm CropLife's suggestions in this submission are adopted, it will support the Government's plan to boost export earnings by creating a more predictable path to registration for companies and unleashing both more and faster access to innovative products to the NZ market.

2.6 To maintain NZ's world-leading growing and farming practices, it is essential to keep innovating to replace older chemistry. The current requirements for and evaluation of the Chemistry and Manufacturing dossiers for agricultural chemicals present a number of challenges widely recognized by applicants. As a result, crop protection companies face greater difficulty in developing and bringing new products to market in NZ than elsewhere. This discourages and disincentivizes the introduction of new and softer tools to the NZ market, constraining the ability of farmers and growers to access new products.

2.7 If Agcarm CropLife's suggestions in this submission are adopted, it will support the Government's plan to boost export earnings by creating a more predictable path to registration for companies and unleashing both more and faster access to innovative products to the NZ market.

3 International harmonization

3.1 This draft guidance document introduces many new requirements and yet addresses very few of the concerns raised with ACVM by applicants / registrants and Agcarm on numerous occasions over the last 10+ years.

3.2 The current proposal would result in NZ chemistry and manufacturing requirements being considerably out of step with other regulators around the world. It is disappointing that despite wide and long-term applicant and Agcarm feedback, ACVM have drafted this document including aspects that have increasingly created unnecessary hurdles, delays, and frustrations. This review is an opportunity to positively resolve regulatory barriers and issues.

3.3 Agcarm supports harmonization with international best practice (rather than the most conservative or stringent) – especially with APVMA. Agcarm appreciates that ACVM also does in some sections within this document where APVMA alignment is referenced. However, in several instances there are significant deviations, especially with reference to the actual practice.

3.4 Requirements for chemistry and manufacturing, on top of what APVMA requires, that are unique to NZ cause unnecessary delays, costs, regulatory burdens, and barriers for registrants and ACVM staff. Furthermore, this results in a reduction in new products being registered on the NZ market – reducing end users (i.e. growers and farmers) access to new and alternative crop protection tools.

[2] www.hortnz.co.nz/news-events-and-media/media-releases/horticulture-post-covid-recovery-strategy/

3.5 NZ crop protection products represent approximately 0.6 percent of global production. At a time when NZ is focusing on recovering from the impacts of the Covid-19 pandemic – we will be particularly reliant on the primary sector (i.e. growers and farmers) to provide jobs, food security and social and economic stability for our country.

3.6 The opportunity to reform and harmonise the current NZ specific ACVM regulatory requirements around chemistry and manufacturing is more vital now than ever. Agcarm strongly requests ACVM redraft this guidance document in light of feedback contained in this submission to address issues raised by applicants and make it more risk based in line with the risk areas manged under the ACVM Act. This will better maintain consistency across products in how they are assessed, now and into the future. Applicants are seeking clearer guidance with clear expectations that are globally harmonised (starting with APVMA).

3.7 Agcarm strongly request ACVM hold a workshop with APVMA and align NZs chemistry and manufacturing requirements to accept packages developed for the APVMA. This has been a long-time suggestion of Agcarm and we would like to offer support in this area to see how this can occur in a way that saves resources and minimizes complications for both MPI, and suppliers, manufacturers and registrants attempting to meet NZ specific regulations, that do not manage specific risks outlined in the ACVM Act.

4 Generic feedback

4.1 This guidance needs to be clear and concise to ensure there is not room for differing interpretation by changes in ACVM staff as this is frustrating and resource intensive for applicants. This causes unnecessary delays and does not manage actual risk.

4.2 Replace the word ‘relevant’ throughout the entire document for clarity. Relevant can be open to interpretation.

4.3 A transitional period needs to be applied when this document is finalized and for new requirements to apply to new products only i.e. not a registration renewal etc. and not retrospective. This would not be achievable within the regulatory resource of applicants and or ACVM and it is not sustainable to do this. ACVM should state a clear date when the new requirements are applicable from and ensure any new requirements are not implemented onto applications submitted prior to that date and a transitional phase of at least 2 years should be implemented. Can ACVM confirm that they will not apply these requirements to renewal of existing registrations?

4.4 Agcarm request ACVM ‘mirror’ the self-assessment ability for minor changes as has been allowed for in the recently refreshed veterinary medicine chemistry and manufacturing guidance document.

4.5 Agcarm are aware that this is a Guidance document and deviations from the guidance can be made. However, it is very resource intensive and frustrating for registrants to provide justifications for deviations from the current information requirements (No 12 2010 document). Agcarm requests that ACVM be precise and prescriptive throughout this new document to ensure expectations are clear and do not alter depending upon individual (i.e. new staff) interpretations.

4.6 Edit the entire document to ensure it is only asking for information pertaining to the ACVM Act in the NZ context to ensure the risks under the ACVM Act (i.e. not HSNO etc) are being managed.

4.7 Given the amount and depth of the feedback in this document Agcarm requests a workshop to be held with ACVM and key crop protection registrant members to discuss the alterations needed and rationale in detail. This is also an opportunity for ACVM to ask registrants questions. This workshop should include industry manufacturing / supply chain experts.

4.8 Within the new guidance document ACVM propose to increase data requirements from what is currently required. Agcarm urge ACVM to consider the following:

- ACVM is currently not meeting statutory timelines. By increasing data requirements, the workload will increase not just for applicants, but also for ACVM. What steps will be undertaken to ensure statutory timeframes are met?
- The new requirements will increase the workload, cost and time to market for local manufacturers, who perform their studies and formulation work in NZ. This reduces the opportunity for new products to be developed in NZ specifically for the market and to the benefit of NZ growers and farmers.

4.9 A number of proposals fall under the HSNO, not ACVM act. Adding these requirements creates a duplication of effort for the manufacturer and government bodies.

5 Section feedback – This has been sourced from multiple members so there is some repetition

Section #	Agcarm Crop Life feedback
3	Amend **impurity** definition to: any component in a technical active substance other than the pure active substance and / or variant which is present in the technical material. Impurities include reaction products, degradation products, contaminants or chemicals added for purposes of extraction or purification. Using the term "impurity" for formulations implies impurities of the active substance and of formulants. Impurities of formulants are only known to the applicant if they are toxicologically relevant and as such are included in the material safety data sheet. All other impurities in formulants are generally not known to the applicant. Therefore, it is proposed to use the term "impurity" only for technical active substances, e.g. (from EU regulation 2009-11):*'impurity' means any component other than the pure active, substance and/or variant which is present in the technical material (including components originating from the manufacturing process or from degradation during storage).* ACVM should not be regulating impurities of formulations or co-formulants. Only impurities of technical active ingredients.
4.2	*"If the product is currently or has previously been registered by an overseas authority, provide any relevant information on product defects or manufacturing issues that may impact the risk profile of the product."* What is ACVMs justification in mandating issues around product defects in other countries? There are AERs for NZ so this requirement is not needed. ACVM need to ensure they are operating under the ACVM Act and focussing on managing those risks. Unless it is relevant to NZ, ACVM should not be requesting this. It is assumed it is not needed unless there is a specific NZ impact? Suggest re wording to make this clearer and remove the word *relevant* and replace with clearer guidance as 'relevant' is open to individual interpretation. Overseas authorities have different approaches and threshold criteria where it comes to "issues" and "risk profiles". It should specify that relevant information refers to relevant information under the ACVM Act when operating in NZ. Past overseas adverse events related to chemistry and manufacturing, which are most likely addressed and resolved by the time a submission to ACVM is made, should not be within the scope of the New Zealand registration.
6	Agcarm assume this only relates to applications for products containing a novel active ingredient or a new source of an existing active ingredient, without an

	APVMA approval (as cross reference to existing registrations is applicable in all other cases). Re-draft this section for clarity.
6.1.1 (1d)	In what circumstances would MPI contact the supplier directly and bypass the registrant? (also relevant to 6.3.1 (1) d), 6.3.2 (1) d), 7.2.1(2) and 7.4.1 (3) as telephone and email is also required)? Remove the request for phone and email to be provided as the NZ registrant holds contact details which can be quickly passed onto ACVM once contact with the registrant is first made. Many currently registered products do not contain this information.
6.1.1 (3)	Needs clarification. The document says these are exempt, but later says *"Evidence of a quality system must be provided for these actives if the manufacturer is not provided"*.
6.1.2	Common (INN) should be removed. International Nonproprietary Names (IN) identify pharmaceutical substances or active pharmaceutical ingredients. It makes no sense in this context of agricultural chemicals.
6.1.3	There is a very large increase in the number of required parameters including physical-chemical properties that have no relevance to ACVM and the risk areas managed under the Act i.e. flashpoint, flammability, explosive and oxidising properties, autoignition temperature, corrosion characteristics. Also, of note is that many of these requirements are not available and indeed are not required for a complete SDS – where "no data" is an acceptable entry. These parameters are relevant to EPA risk areas managed under HSNO. Agcarm suggests changing this text to make it clear provision of parameters is optional or remove altogether. If this is not changed, it will create a significant increase in administration for applicants for no risk management of ACVM areas. Data may not be available on all these parameters for every source (e.g. for APVMA approved products where parameters are already assessed by APVMA and not disclosed). Therefore, it may not be possible to provide the purity of the test substance or the method used. A reduced suite of information should be acceptable for active ingredients that are already approved (if required at all) as the properties of the active are already characterised. Insert a sentence that this is for actives that do not have APVMA approval (i.e. these properties are not required if the active is APVMA approved). ACVM also need to provide clarity as to what is deemed APVMA approved? Is providing the APVMA approval number enough or do ACVM expect to see the Certificate from APVMA? In case of the Certificate, this will add considerable time to the processing of the application and including the application being rejected at pre-screen. Stereochemical properties are already addressed in 6.1.2 Identification and chemical structure. *If relevant, the structural formula should include stereochemical properties of the active ingredient. For example: geometric isomerism (cis/trans, E/Z), the number of chiral centers and the configuration of each center.* For APVMA approved actives it is not clear if a statement would suffice or if the studies from where the values were derived are required to support the information provided? Suggest re-wording for clarity.

	Physical Chemical properties (active): If the requirements apply only to new actives into NZ, it should be made clear in this section. If this is not the case can a reference to existing registrations be made for actives that have already been approved for use in NZ? Does the request for a description of methods used to generate the data apply to existing actives? For existing actives data is often taken from published literature, where methods are not always mentioned, would applicants still need to provide them in this case?
6.1.4 (2)	CoAs show purity / concentration of the active in the technical active and formulation only. There appears to be confusion within ACVM on what a CoA is. Include the following definition in section 3: Certificate of Analysis (CoAs): *A document issued by Quality Assurance that confirms the product meets its product specifications. CoAs commonly contain actual results obtained from testing performed as part of quality control of an individual batch of a product.* A COA will not normally determine impurities of a formulation (mixture). The level to which an impurity is measured at should also be stated – i.e., above levels that impact toxicity (HSNO or GHS classification).
6.1.4 (4)	Harmonise with APVMA – just purity of the active. This becomes the specification of the TGAI. EPA set the specification differently due to a lack of harmonisation. Agcarm appreciates the (four country) logical sequence but there will be differences for NZ as NZ EPA tends to align with the EU which is often different and causes major issues for NZ applicants as most often the product and active are already registered in Australia and the data package accepted by the APVMA is used for NZ. Align with "designated authorities" as specified in WorkSafe and HSNO regulations. Why does ACVM evaluate impurities (impurity profile is section B2 of the PDS)? All other regulators do this only to look for impurities of toxicological and ecotoxicological significance, but this is not ACVM's mandate in NZ. Remove all NZ specific requirements. This is causing massive regulatory delays, barriers and resourcing and compliance costs to meet ACVMs unique regulations that are out of step with every other country in the world. ACVM and EPA need to align. Companies cannot produce unique to NZ data or conduct extremely expensive tests for the very small NZ market. Already new manufacturing sites are not being added to registration packages due to compliance costs. For the same product in Australia there is usually multiple options, for NZ there may be only 1 or 2. As pandemic events of 2020 have shown this causes a risk in terms of security of supply if one manufacturing site, region or country shuts down and alternative manufacturers are not approved for the supply of the active and / or product is halted immediately.
6.1.4 (5)	This needs to be aligned in the context of ACVM Act relevance only – often EPA application has not yet been made due to data protection and / or the EPA application is not progressing at the same speed as the ACVM process. This would

	cause unnecessary delays in the process for no risk management under the ACVM Act.
6.1.5 (1a)	Should be 1 g/kg or 0.1% to harmonise with international best practise. This appears to be a historical error. Companies comply with this lower level given it is an international limit.
6.1.5 (3)	Unclear what the risk management rationale for this requirement is? Should be corrected to say it is only a requirement if it is relevant to the chemical structure or properties for the active - so only then it is applicable? The impurity profiles by definition account for impurities of toxicological significance and all other impurities present at ≥1 g/kg. There is not a need to have a separate requirement around this.
6.1.5 (4)	Hexachlorobenzene (HCB) – MPI and EPA's maximum limits are different. ACVM 50ppm vs EPA 100ppm. The MPI maximum limit is not published. The two NZ Government regulators of crop protection products need to be aligned.
6.1.8 (1)	Inconsistencies need correcting - states three recent batch analysis are required, including one of commercial scale. However, 7.2.1 (2), adding an active ingredient source, states one recent commercial scale batch analysis only. Does ACVM require one or three? Should only apply to new active ingredients, if at all, otherwise it should be one batch. Many active ingredient batch analyses are 5-batch analyses, which are typically performed infrequently to determine the impurity and purity profile of the product, then a maximum age of 5 years should apply (not 2 years as proposed) to align with overseas regulators. Confusion appears between a 5 (or 3) batch study and a certificate analysis of a recent batch. ACVM have confused terms - batch analysis is a study likely older than two years. APVMA require a CoA to be signed within the last two years. What risk is this managing under the ACVM Act for requiring the shorter time period of a CoA? The vast majority of products registered in NZ rely on APVMA approval number - need to reference this. Batch analysis is not needed for existing actives for all sources previously registered. This only applies if registering a new active where the source of active is not registered by APVMA or NZ. Insert a sentence for clarity. As APVMA no longer update their website with the APVMA approval number. As a result, ACVM have been requesting the Certificate with the information. This has led to significant delays in previous applications while waiting for APVMA to issue these Certificates whilst managing no risk. A better more streamlined process is needed. There are two stages of product development. 1. Develop the product 2. Scale up Why do ACVM require justifications for pilot batches? Applicants should not have to provide relevance justifications. ACVM can rely on commercial batches so why is there a need to argue the point when the commercial batch analysis confirms

	what the pilot indicates? It is an administrative waste of resources for no risk management. Other regulators approvals come with a condition that commercial scale batches must be analysed and the results submitted within a prescribed timeframe (usually to align with when the applicant indicates the commercial scale production to commence). The acceptance of pilot scale data for new sources of active ingredients is a relatively new practice and the exact APVMA's requirements are still a bit unclear. For clarity - Include the following definition in section 3 of the document: Batch analysis (taken from APVMAs definition): *An analysis for active constituent, isomers and impurities content carried out on five separate batches of production material. This analysis provides evidence that the material conforms to the specifications, ie it is within the certified manufacturing limits.*
6.1.8 (2) k)	Batch reports are prepared according to GLP. Promulgation of GLP via OECD allows in many countries to overcome this enquiry for "raw data", as GLP is a management system to globally ensure consistent quality of performing and documentation of data. Why does ACVM need to see the raw data? This requirement could apply to only non-GLP reports? If this is the case amend this section for clarity.
6.1.8 (3)	It is not clear if technical justification is required only when a commercial batch CoA is not provided or in all cases (e.g. does a '2 pilot + 1 commercial batch' also require technical justification?). Also, the guidance is not clear regarding the need for a commercial batch CoA. Would a commercial batch CoA be required or '3x pilot + technical argument' suffice (e.g. a commercial batch CoA would not be required to support the TGAI manufacturer and no Condition 86 would apply)? Section 6.2.8 (4) for formulated products clearly outlines commercial batch must be supplied and additional conditions that may be imposed. This section needs re wording.
6.1.8 (4)	Batch analysis b) minimum purity of active ingredient – add *if relevant* For some Technical concentrate, it is impossible to have the isolated active substance, thus no analysis is possible (only calculation).
6.1.8 (2 I, j, k) 6.1.9 6.1.10	These requirements should not apply to active ingredient sources that are APVMA approved as methods have been suitably verified by APVMA. Add a sentence to this affect and re word / delete. Methods, validation reports and raw data may be considered confidential information, that technical manufacturers may wish to supply directly to ACVM this will cause further delays to the registration process. Local manufacturers often use third party sourced products and the proposed new requirements means that these companies will be forced to be restricted to fewer options. This will lead to increased cost not just for local industry, but also for growers and farmers.

	Increasing data requirements in this area gives an advantage to global manufacturers over local NZ manufacturers. As additional resources and time is required to compile additional data.
6.2.2 (1a i, ii)	ACVM are requesting manufacturer specifications for non-actives. This does not manage any ACVM Act risk areas. This currently causes significant time delays and frustration for applicants and suppliers (and failed pre-screens at no fault of the applicant). This is also not international best practise as no other countries implement this requirement in the way that ACVM does. Agcarm is extremely concerned this appears to be mirroring GMP framework of Veterinary medicine products. Agcarm strongly rejects this for crop protection products. As applicants do not know what products ACVM hold information for this should not trigger a failed pre-screen and it should not be required at all. Agcarm request ACVM provide examples of where this extra information requirement has uncovered risks (to areas that ACVM manage) that would otherwise not have been detected? Do ACVM have any assurance from manufacturers that they will not in future change their specifications? If not, there is no benefit and or risks managed. The SDS for the product sufficiently describes hazards of non-active ingredients (however, these hazards are relevant to the HSNO Act). The FAO Specifications for Pesticides Training Manual states that "*FAO / WHO specifications do not provide clauses for control of formulants ("inerts") or formulant impurities. Information on formulants are confidential. Many formulants are complex materials which, although having appropriate physical characteristics, may vary in composition, over time and around the world. National registration authorities may provide controls for the identity and content of formulants, although identification and quantification of certain formulants are technically challenging. Formulants and their impurities are generally indirectly controlled through the physical properties and storage stability of the formulated product*". Why is NZ, which is a very small market, imposing unique requirements so out of step with global regulators? It should be noted the APVMA requirements appear to be identical in wording in this respect but the interpretation / implementation practice by ACVM is significantly different. This information is requested by APVMA in extremely rare situations, in fact so rarely, that most experienced applicants in Australia are not even aware the requirement is the same as is imposed in NZ.
6.2.2 (3)	Provide further details? This is a change from the current requirements. Need to update PDS. This section also refers back to itself. Editing is required to make ACVMs expectations in this section clear.
6.2.3 (1)	Agcarm strongly rejects the need for this requirement as crop protection products do not operate under the GMP framework.

	This would increase cost of compliance, cause unnecessary delays and add more work to assess areas that do not manage ACVM risks. Parameters g, h, i, j and k are of no relevance to ACVM risk areas and are only relevant to risk areas covered by EPA under HSNO. They should be deleted. If this was to remain in the guidance, it would only serve to increase the cost of compliance for the small NZ market whilst not managing any ACVM Act risks. Adding these to the ACVM requirements is a duplication of regulation by two government departments. If new parameters (such as explosive properties, oxidizing properties etc) for new formulations are required, this will increase the workload, costs and time to market for local manufactures, who perform most studies in house. Increasing data requirements in this area gives an advantage to global manufacturers over local NZ manufacturers.
6.2.4	Shift to 6.2.9, which is more logical because an overage is not to be declared provided the Active Substance content for each batch stays within the FAO limits. Nominal active substance content is what is on the label.
6.2.7 (3 & 4)	**Additional guidance Impurities** Agcarm strongly recommends deleting this whole section. The requirement to monitor and report toxicologically significant impurities or impurities >10 g/kg in excipients should not be required unless it has been identified by EPA that there are toxicologically significant impurities of concern in the excipients (or risk of their formation in formulated products) relating to a food safety concern. There is no practical way this could be routinely undertaken by manufacturing companies. Excipients are purchased from professional companies whose job it is to ensure their product is fit for purpose. ACVM seem to be indicating they require data on concentrates at even lower levels than impurities in the active. Applicants are not required to inform ACVM if there are impurities in the active of these levels (so this makes no risk management sense). This is not relevant to the ACVM Act as a food safety concern. Toxic impurities come under the HSNO Act to manage not ACVM. Remove references in all instances in the document to toxic impurities. ALL impurities in formulations (including impurities of the technical active ingredient and all co-formulants) are accounted for in the HSNO approval. This is achieved by certain hazard classes usually covered by the studies on the actual formulation (i.e. tox 6-pack: acute oral, acute dermal, acute inhalation, skin and eye irritation and skin sensitization). In other hazard classes (carcinogenicity, developmental toxicity, ecotoxicity) mixture rules are used accounting for ALL hazards associated with all components in the formulation. This is all covered under the HSNO Act in applications to the EPA. What is this information used for in ACVM risk management? It is redundant and out of alignment with APVMA & FAO. The information provided in the SDS is sufficient. Refer to points made for 6.2.2 (1) a. i, ii.

	Critical excipients – it is not clear what risk/s under the ACVM Act are being managed here by ACVM asking for this data. It seems the intent is to set a standard while addressing generics. However, there is no clear pathway on how generics would be able to demonstrate equivalence in such cases. Importantly, what would be the ACVM requirements where a product contains a critical excipient - how is this judged? How would ACVM handle / analyse this information? What is the definition / criteria? Can ACVM clarify why this is needed? Every excipient is critical in the formulation for a reason - each have functions (as specified in the formulation table) to enable the product to work efficaciously etc. Agcarm questions what risks ACVM is attempting to manage. APVMA do not require this – remove to harmonise. For equivalence between similar excipients further guidance from ACVM is welcomed. Registrants should be able to exchange co-formants (using different trade names) if they are the same without notification to ACVM.
6.2.7 (5)	Allowance is needed to allow multiple trade names to be used as no risks are being managed here if it is simply a different trade name (administrative change only that could be notifiable upon registration renewal i.e. not approval by ACVM each time).
6.2.8 (1)	It seems the intent of this section is to ensure a commercial batch CoA is provided to demonstrate compliance with the proposed specifications for the product – as part of a QC. In this context, it is irrelevant to talk about pilot batches. Pilot batches are typically produced during the product development phase. As a CoA from a commercial batch must be provided there should be no need to justify the relevance of the size of pilot scale batches used in the product development process. If the commercial batch CoA demonstrates compliance with the specifications proposed during the development phase, the manufacturing process is automatically validated. There is no need for justifications. Ultimately, the commercial batch speaks for itself and if in compliance with the proposed specifications there is no argument. If there is non-compliance and adjustments to the specifications are required, some degree of argumentation could be expected and if applicable the product specifications amended. If the idea is to present the guidance as the events happen, this entry 6.2.8 should be the last item and the intent of presenting a commercial batch CoA is to validate the whole product development before the product is presented for sale. Remove 1a last sentence as it is the applicant's responsibility to show validity. 6.2.8 Batch analysis, 6.4 Stability Testing, 6.5 Analytical methods + validation (Product) The current requirements adequately meet needs in this area. Providing this additional information will add a strain on both applicant and ACVM staff resources for no additional risk management. Agcarm would like to understand what risk management (that does not currently occur) would be achieved by supplying this data? **Batch analysis requirement for each site of manufacture for products** Agcarm strongly requests the removal of this requirement (also applies to section 7.4.1) for additional sites. If there is no change to the manufacturing process, the ingredients or the specification and an initial batch analysis has been provided, there should not be a need to provide this for each and every site. This requirement is also out of line with other regulators, for example in Australia, an additional

	product manufacturing site is a notifiable variation and is approved within a couple of days. In summary this requirement belongs with compliance monitoring. Commercial batches are usually not available before registration and therefore COAs for them cannot be provided. There is no such requirement in Australia. Time zero analysis of a laboratory or pilot scale batch in the stability study is accepted as a batch analysis for ALL manufacturers who follow the same manufacturing process and formulation. Adding a new source of manufacture for an agrichemical in Australia is a notifiable variation (only the new address is required and the following declaration: *I declare that proposed variation will not affect the formulation of the product*.). Variation here = adding a new site of manufacture.
6.2.8 (2)	Time zero – elsewhere the document requires commercial scale. Need to allow pilot / lab scale batch or commercial. ACVMs suggestion of a commercial scale batch does not add any buffers in terms of risk management. There are two stages of product development. 1. Develop the product 2. Scale up The second stage includes QC processes. Agcarm strongly requests ACVM align with international best practise. ACVM controls allow for provision of a commercial scale batch tested against the declared product specifications to prove the commercial batch is within these. There is a large difference between QC and QA. Should place control 86 / 101 on the product then allow registration to proceed. Applicants should not have to justify every time or make arguments to explain the relevance of pilot batches. Stability study sits in the product development phase. It is possible that at this stage several parameters that are not necessarily applicable or even relevant in the context of QC are tested and in most cases the study is performed on a laboratory or a pilot scale batch. In the absence of a batch analysis, the guidance should be restricted to item (4). As per international best practise - no release and expiry specifications are needed because there are robust QA systems in place to ensure commercial production is in line with expectations for a large commercial scale or smaller pilot batch.
6.2.8 (4)	This indicates a requirement above global regulators and causes unique to NZ issues. There is no need for commercial scale batches. This could be checked as part of compliance activity. Agcarm suggests that MPI staff saved time in not assessing unique to NZ regulatory requirements that would be better spent on compliance activities to test that batches are compliant with specifications instead. Stability studies are not on commercial scale batches and performed specifically for NZ should not need to justify the development process that is applicable to all crop protection products that go from development to commercialisation.
6.2.9	**Product specifications** Registrants have previously raised concerns numerous times over a number of years about product's specifications with ACVM. Agcarm is disappointed that these have not been addressed in this document.

	(1) release must meet specifications, not test every batch to confirm. Change release specifications to **product or formulation specifications** - these are NOT QC specifications. There is just one set of specifications, which are the product specifications. Any product in the market is expected to comply with the specifications for that formulation type. It seems ACVM is referring to "Release Specifications" in the context of QC. By referring to Appendix 1 it implies that those parameters (based on FAO standard for product development) are the standard parameters for QC. Please note these parameters (as per FAO) are not intended for QC, but product development. The use of such parameters may be more relevant in the QA context (note the difference between QA & QC). Under commercial production, the formulation is fully developed and balanced. To test all (or most) parameters listed in Appendix 1, or even use this list as the standard for QC is not practical or standard practice. As an example, for liquid formulations, TGAI content and specific gravity (SG) may suffice for QC purposes. This is because the correct SG and compliance with the expected TGAI content suggests the formulation is balanced and by default all parameters tested during development phase should be complied with. Specification rationale *1) In case the proposed specification does not follow FAO recommendations for the respective formulation type provide a rationale explaining how the specification proposed for the formulated product will manage the risks associated with the product's manufacture, storage, and use. This includes both the parameters being chosen and the value or range proposed as acceptable for those parameters.* The FAO manual on specifications contains recommendations for each formulation type and for each test parameter, which ensure acceptable performance and impact on humans and environment. Therefore, additional rationale is only necessary in case of deviations from FAO manual. This should be made clear in this section. This should be on exception only. If a product is demonstrated to be manufactured within globally recognised limits, then no explanation should be required as it is self-evident the product is fit for purpose. Internationally, the FAO manual for product development sets the standard parameters for each formulation type. The reasons for each parameter are set in the manual. It is possible that other parameters may be selected at this stage, just so there is a wider understanding of the physicochemical performance of the product. Expiry specifications – carrying out stability studies on one batch to test the concentration of the active before and after the storage (nominated shelf life). Then ACVM assumes all other batches will be the same and this is only appropriate for veterinary medicines NOT crop protection products - again a NZ specific requirement that makes no regulatory sense and manages no ACVM risk areas. Agcarm strongly request the whole expiry specification section is REMOVED as it is covered by the shelf life where the product must not fall outside of the product specifications. If it does then compliance action should be taken. It is out of harmonisation with other countries' regulations. There is a need for **only** one set of specifications for the whole product. Global suppliers / manufacturers do not understand this unique to NZ requirement and it causes unnecessary delays and regulatory burden on applicants and further makes NZ an unattractive place to register crop protection products. Unique to NZ requirements are very challenging

	to meet and should be abolished where they do not manage ACVM specific risk areas. If compliance activity showed that this needed addressing for a particular product / active then this should be a separate registrant / ACVM interaction specific to those actives. Packaging specification requirements have been increased against the current standard. 1b is not relevant and should be deleted. 2d – closure relates to HSNO / EPA. ACVM have no jurisdiction to manage the shape / appearance – it is irrelevant and does not allow for flexibility in changing the product in the future as new packaging options in terms of shape / appearance / colour etc may develop. This only serves to increase the administrative burden for both applicants and ACVM and results in the need to make applications to alter the PDS / registration dossiers for zero risk management gains with regard to the ACVM Act. (2) and (3) are addressed by the EPA packaging requirements and not relevant to ACVM. They should be deleted. Permeability is addressed in construction material in (1) d. It appears there is no longer a requirement to apply for a variation for additional packaging sizes within an approved range (just notify ACVM by providing an amended PDS in subsequent renewals / variations)? Does this mean only size variations are allowed within an approved range? What are the triggers for notification or variation within an approved range in the context of the information required in (1 - 4)? For (2), how are these related to risks manages under the ACVM Act? These are more relevant under HSNO as they relate to risks associated to transport / storage regulations. (4) not sure what this means? What is the process in place for granting an approval for recycled plastics? <u>Further information, background and justifications for removal of Release and Expiry Specifications</u> ACVM is the only regulator who has a requirement for separate release and expiry specifications, and who expects testing of all parameters in the FAO manual to be tested for every batch. The purpose of undertaking stability testing is to demonstrate that the manufactured product will be within recognised acceptable limits at manufacture, be that APVMA or FAO, and will experience minimal change during storage / the nominated shelf life. The <u>product specification</u> can be based on results of the stability study. If inputs and manufacturing process do not change then there is no reason to expect there will be any significant change to these parameters. There should be no need for ongoing testing of all parameters. Typically manufacturing companies test only a few critical parameters for <u>QC</u>, such as active concentration and density or other key indicator parameters, from which any deviation from the specification would clearly signal if there was an issue with the batch that warranted further investigation.

	Having a separate expiry specification has missed the intention of product specifications. The FAO Specifications for Pesticides Training Manual states that "specifications for pesticides are developed by the Food and Agriculture Organization (FAO) and by the World Health Organization (WHO) to enable good- and bad-quality products to be distinguished, using simple, robust and well-validated test". They further state "test methods for physical properties are simple models; they do not demonstrate field performance". Therefore, if a product is within globally accepted limits at manufacture (as demonstrated in stability study testing) then it has been demonstrated to be a good quality product, and there is no need for a separate expiry specification. These requirements mean that the NZ specification will never align with global specifications. Yet ACVM insist documentation provided only shows a NZ specification. This is unrealistic as all other countries conform with the global FAO specification, and testing is undertaken on that basis. It should be these results that are considered. This NZ specific requirement causes considerable frustration for global manufacturers. Agcarm strongly request ACVM Harmonise with APVMA and remove the requirement for an expiry specification and remove the requirement for all parameters from Appendix 1 release specification parameters. If this is not acceptable Agcarm members request a meeting with ACVM to discuss and discover what unique to NZ risks are attempted to be managed by these requirements. ACVM say release specifications are those that the product meets at release. ACVM ask for a separate set of tests (QC specifications) in the manufacturing method section. If these are the same, then why provide them twice on the PDS? It appears from this that ACVM realizes release specifications are overall product characteristics. Yet when applicants are asked to provide a CoA for a formulation, it is expected to exactly follow the release specifications. If ACVM compliance means that at any point a manufacturer must be able to produce a CoA with all release specifications for a given batch, these can only be the QC specifications, not specifications defined as product characteristics. So what are the *release specifications*? Product characteristics or QC specifications? If the former, ACVM cannot expect registrants have a CoA for any batch with all of them. If the latter, ACVM cannot expect registrants to follow Appendix 1. The requirement to provide expiry specifications is out of step with international regulators. Provision of expiry specifications for the active is not necessary for most crop protection products (with the exception of older actives, such as those actives listed in Appendix 3 that require real time stability studies due to their degradation properties) as they do not degrade and are stable through their shelf life provided they are stored correctly. This has been a major issue for registrants for some time which can be easily solved by harmonizing the requirement with APVMA. **The problem:** The requirement to provide expiry specifications is an issue primarily because global manufactures are not familiar with the information required as they do not provide this documentation to any other regulatory agency. Obtaining the

	information takes considerable amount of time, is very hard to extract and (therefore money) for the registrant and technical and administrative staff at ACVM spend unnecessary time communicating the requirement for no regulatory benefit and risk management. This currently results in pre-screen declines, halts the registration process, creates a backlog and causes significant delays. It is unclear what risks this requirement was set to manage. With veterinary medicines, this is an acceptable requirement due to the unstable nature of many actives, as well as for animal welfare and efficacy reasons. However, there are not the same risks to manage for crop protection products as actives are stable. With normal stock rotation, products are sold on and used within two years. On occasions where this period may be longer, the stable nature of the active means that the product can still be safely used without risk to those that ACVM manage i.e. residues, efficacy, crop safety etc. If not used within the 2 year period, some companies will undertake tests to ensure the product is still within specification. **Benefits:** Harmonizing with APVMA would benefit both ACVM staff in terms of savings in time and resource, as well as registrants and international manufacturers. Move section 6.2.4 Overage to this section to form part of the product specifications. If ACVM agrees to the comments in this section, Agcarm would be happy to draft a product specifications section for ACVM.
6.2.10	This section implies the APVMA standard applies for the impurities. However, 6.1.4 (4) outlines that NZ EPA takes precedent over the APVMA standard, as follows: *"MPI harmonises with the following agencies for standards for an active ingredient (in this order): NZ EPA, APVMA, FAO."* Insert a clarifying sentence re APVMA to ensure both sections are clear.
6.3.2	**Additional Guidance –** compliance with the "ACVM Registration" goes beyond the Chemistry Section. For example, there are conditions imposed on the product that are to be complied by the end user (e.g. Condition 83 – MRL compliance). These conditions are an integral part of the "ACVM Registration". Rephrase to *"releases the product for sale"* as it narrows down the scope to Chemistry and Manufacturing and focuses on the intent of this document only.
6.3.3 (1, 5 & 7)	It should be acceptable to provide a written description <u>or</u> a flow diagram, regardless of the complexity of the process. Flow diagrams are not routinely produced so this is just an extra administrative burden on applicants to draw a flow diagram that provides no benefit or risk management. What is the rationale to request the "typical batch size"? It seems the intent is to address commercial scale production- this means a statement identifying the batch as a commercial batch should suffice. Batch size range should be removed. This varies with commercial demand and has no relevance to product quality. What size is a 'large' batch size? Batch size is driven by demand and is irrelevant for ACVM risk management – remove.
6.3.3 (1) g)	This is a new requirement. As mentioned above, this will further increase administrative burden and complexity in drafting these descriptions – for no risk management outcome. The active and product have to meet the quality criteria as

	defined by the specification and methods. What value and risk management under the ACVM Act is this extra step adding?
6.3.4	This is not required and or imposed by other regulators - it is irrelevant. It is extremely for other regulators to identify this as a deficiency if not provided. What ACVM risks is this managing? It is an extra compliance requirement. Remove this section as the information will be generic and will not provide any additional risk management. A review of a whole manufacturing plant would be needed. Suggest that ACVM increase compliance activity as a practical step if this is an attempt to manage the risk of contamination. Agcarm is in no way opposing that a robust decontamination processes should be used to control contamination. What is opposed is the requirement to include this in a specific product registration dossier. This lies with compliance monitoring. The process will vary depending on what the active ingredient and formulation types are produced in a line, and this likely changes over time. Therefore, this requirement could be quite onerous and may not cover future risk so provides no real value or assurance / risk management. Many manufacturers are ISO accredited and therefore have contamination prevention plans that have been audited by ISO.
6.4	Delete the whole of section 6.4 (1-7) and go straight to 6.4.1, which is sufficient and clear. This section starts by explaining that *"Unlike veterinary products, most agricultural chemical products do not have a shelf life or fixed expiry date under the ACVM Act."*. Why would ACVM compare agchems with vet meds? This sentence does not add value. Throughout this section, it appears ACVM is attempting to invent and implement NZ specific regulation. Agcarm strongly disagrees with this approach. The aim of a stability study is to ensure that the properties of formulations are not adversely affected by storage conditions and to assess their long-term storage stability, with respect to content of active ingredient and certain physical properties. The second part of the opening sentence is not accurate: *"For the bulk of agricultural chemical products, data should confirm that the formulated product will remain within specification for at least two years, when stored in its unopened original container, away from direct sunlight, at or above 20˚C ('normal storage conditions')"* – literally this can only be achieved if the study is conducted as prescribed (e.g. real time stability study with temperature set at 20˚C). This contradicts the information outlined in 6.4.2. 1L pack sizes are representative of larger pack sizes. It is physically impractical to test 10+L and drums and is again a NZ specific requirement. Remove. (1) Humidity and light are not a requirement of APVMA or other jurisdictions. They should not be included unless these parameters are known to affect storage of the product due to the active properties (i.e. biologicals). Insert – only required "if applicable" (and there should not be a requirement to justify why it is not applicable for the majority of products).

	(7) Remove. All crop protection products are dissolved or diluted before use, and stability testing parameters already cover this. If a stability study shows tests within normal range, then it does not require further discussion / justifications for ACVM risk management.
6.4.1 (3)	Stability studies are typically conducted only in 1L container, not in a variety of pack sizes. Delete this section.
6.4.1 (10)	Delete. The size of the container has a limited effect of storage (chemical and technical properties). Comparative storage tests in 1L and 25L containers on selected SC and FS formulations have been performed by companies and only insignificant differences found between both pack sizes. Storage trials in large containers use unnecessary resources as well as material and lead to unnecessary incineration of large amounts of chemicals which is an environmental risk that can be eliminated by ACVM allowing smaller pack sizes to be used (without a need for justification of smaller sizes). From APVMA requirements[3]: *The APVMA does not require additional stability data for an increase in primary pack size from that used in the stability study. The surface area to volume ratio of the product reduces as the primary pack size increases, and the interactions between the product and packaging become less significant.*
6.4.1 (6)	This is irrelevant and occurs all the time.
6.4.2 (2)	Delete – it is not necessary and does not manage any ACVM risk areas. Unclear and not in line with APVMA. As currently worded it implies ACVM could request a real time study for any novel compounds. It seems the intent is to limit this to situations where impurities of toxicological concern may develop over time. If this is the case, be specific and require: 'Real time studies are required for compounds where impurities of toxicological concern may develop over time'. As presented, it brings uncertainty and implies ACVM could request a real time study from any new compound regardless.
6.4.3	MT 46.3. has been superseded by MT 46.4 (presented in Braunschweig 2019). (1) 14 days duration at 54°C or alternate conditions as specified in CIPAC MT 46.4, considered to support a 2 year shelf life if specifications are not exceeded. CIPAC MT 46.3 / MT 46.4 states more conditions than 14 days duration at 54°C or 8 weeks at 40°C which are all equivalent and considered to support 2 year shelf life. (4) What happened to FAO tolerances for products with different concentrations? 5% is applicable for products containing 250-500g/kg(L)? If the active content degrades by >10% of the initial reading, or there is a change of concern in any parameter, a suitable interim shelf life may be granted while a real time study is undertaken. Usually, an increase of active content is not realistic. For decrease in active content it is assumed that a change of up-to 10% does not negatively impact biological efficacy (see FAO/WHO Manual on PPP Specifications). Suggest ACVM align the acceptable decrease with other legislations, e.g. EU where up to 10% decrease of active content is acceptable to support a 2 year shelf life.
6.4.4	There is a lot of text introducing the section. If there are instances where real time is not acceptable, be explicit and do not rely on an example. "Additional guidance"

[3] https://apvma.gov.au/node/1042

	is not in line with international practice for agricultural chemicals. If it is 'recommended', ACVM should confirm that such a requirement is not enforceable and or does not have to be justified if it is not included? It is to be provided or optional? If it is not a mandatory requirement – delete or move to an optional appendix. Real time studies for chemical actives, a shelf life below one year is not realistic to support a product on the market, therefore the additional time points should be oriented on the expected shelf life. For microbial / biological actives shorter and variable test intervals may be useful to support very short shelf lives. Re word: **Additional Guidance** For products where a shelf life of less than 2 years is expected, it is recommended to include interim time points, e.g. at 12 months or 18 months to support a shorter shelf life of products based on chemical actives. For products based on microbial actives shorter time intervals may be more relevant. A reduced shelf life will be assigned if there are no interim results for assessment.
6.4.5	Does this mean all liquid formulations not supported by a cold-stability study will automatically attract a mandatory label statement warning against exposure to low temperatures? If the aim is the provision of cold testing, delete first part of the sentence and say: "Cold-stability testing should be carried out at 0 ±2 ˚C or lower for seven days (CIPAC method 39.3) for liquid formulations". If this proposed statement is accepted, then will it be applied as stated? Recently an Agcarm member proposed a label warning against exposure to low temperatures and ACVM requested additional justification as to how it will be possible in certain regions and seasons of NZ (ie the South Island in winter). If the label contains this warning, then the responsibility is on the user to follow storage instructions. Anything else is impractical regulation.
6.5	Clarify that the METHOD should be validated NOT the site. APVMA do not require this, it is incorrect. Site by site is over regulation. The method validation validates the method and not the site using the method.
6.5.1	**Additional Guidance** Accept validation according to SANCO requirements, not just APVMA requirements. Many products registered in NZ are developed for the EU market, and SANCO validation therefore satisfies the requirements of a much larger market than Australia and NZ, and should be an acceptable alternative to APVMA validation requirements (as is the case for the current ACVM No 12 document). The APVMA do not require a method validation for each site where the method is used.
7	(2) Define "approved product information". Would it be synonymous with the contents of the PDS? (3) Not necessarily. According to this document, ACVM intends to waive this process in certain occasions (see 6.2.9 Packaging Specifications – Additional guidance; 7.2.3; 7.4.1). (4) Is this document guidance or a requirement?
7.1 (1)	Alternative excipients. Only allowing one trade name co formulation increases cost of compliance for no risk management. Composition etc is valid but could improve on original then CAS# and generic co formulation then no application should be needed. For APVMA this is the situation. Only a record needs to be kept on file by the registrant.

	Changes to approved formulation details: Agcarm would welcome ACVM guidance what is considered a 'major' vrs a 'minor' change and what data is required in each case.
7.2	Changes to approved active ingredient manufacturer(s) Technical rationale and/or data to confirm equivalence of the proposed source of the active ingredient to currently approved sources. Contradicts requirements for new product, where three batches are required? If the requirement for a new product means new product containing new active to NZ, this needs to be made clear throughout the guidance. There is a need for more explanation on what acceptable methods of proving equivalence would be. Having to provide full equivalence information would be cost prohibitive to introducing new technical sources and limit the ability to manage technical shortages. It is difficult to build an equivalence argument without knowing the manufacturing (synthesis) pathway of the molecule. This information is usually confidential to active manufacturers; therefore, it will be difficult to manage such submissions. Increasing data requirements in this area gives an advantage to global manufacturers over local NZ manufacturers.
7.2.2	Delete as the wording is misleading. It would be extremely rare for a product without an active substance to be produced as a crop protection product then have no active manufacturer left.
7.3.1 (2)	Last row - why is ACVM requiring toxicological data? This is assessed under the HSNO Act. Delete. This whole document needs to be edited to harmonise with APVMA and using APMVAs approval numbers where the active has already been examined.
7.4.1 (3)	Delete the reference to the procurement of raw materials in third row. Section 6.3 does not make any reference to procurement. Section 6.3 addresses raw materials in the context of manufacturing processes. Manufacturers manage the procurement process from raw materials to the packaged product. Fourth row references 'data to demonstrate' – what data? Remove – this is to do with compliance and the next box covers this aspect adequately in terms of a batch analysis is to be provided. Also, the batch analysis is the evidence required? Delete: *"Evidence that the batches conformed…"*.
7.4	What is a technical concentrate? Does ACVM mean an inert ingredient (other than the TGAI)? Align with APVMA and make this a notifiable variation only where there are no changes to any aspects of the new site. ACVM are creating very substantial issues currently and increasing administrative paperwork required for NZ specific requirements for no risk management under the ACVM Act causing NZ to lag behind. Align with APVMA. The risk is a real- life practical problem - with this impractical regulation creating less registered sites for NZ crop protection products. If a pandemic / natural disaster or other unforeseen event occurs at one or more manufacturing sites and there is no other approved sites - production ceases and

	product is no longer available at critical parts of the growing season for growers / farmers etc. There are more sites approved meaning in these instances the product/s would then only be available to Australia end user competitors (ie growers, farmers etc). ACVMs regulatory practises being out of step with global regulations is causing a real-life practical risk. Risk of less new actives, new formulations and sites being registered on the NZ market.
7.7.2	Delete as testing larger packaging size is considered representative for smaller ones.
7.7.3	Agcarm greatly appreciates the variable notifiable variation and is pleased that ACVM have recognised this opportunity for a terrific step forward and Agcarm congratulates ACVM on this.
7.7.4	This is a wonderful improvement and Agcarm congratulates ACVM on this sensible regulatory approach.
Appendix 1	Re insert and include full list of all formulation types as is in the current No12 ACVM document. See comment above in section 6.2.9 – these protocols are not tested for every batch as is intended for development NOT QC. Product NOT expiry specifications – see section 6.2.9 for Agcarms justifications on this topic. Selection of Formulation Types is incomplete and partially differing from FAO / WHO Manual standards, e.g. FS missing; proposal to check and to align with requirements in the FAO/WHO Manual. Include that requirements in the FAO manual should be used where there is no information given in the NZ guideline. Aerosol Dispensers Remove odour. Testing of odour by actively inhaling fumes from a formulation is not complying with HSE/HSWA regulations and therefore not required any longer in many legislations (e.g. EU). Only for Formulation Type = AE, the test “Odour” is specified, delete the requirement to align with other formulation types where Odour is not required. Aqueous Capsule Suspension, Gels and Concentrate, Tablets, Water-Dispersible Granules, Wettable Powder: Suspensibility MT184 now MT184.1. New MT version has been adopted by CIPAC www.cipac.org/index.php/methods-publications/status-new-methods Emulsfiable Concentrate, Emulsion (Water In Oil) And Emulsion, Oil In Water Emulsion characteristics: MT36.1, MT 36.2, MT 36.3, MT 173 or MT 183 Emulsion characteristics MT 36.3Acc. to FAO/WHO Manual, MT 36.3 is the only method for testing emulsion stability. Gel for direct application Refer to wording of CropLife TM2 (7th edition, March 2019). Gels: remove ~~Miscibility, Emulsion characteristics, Wet sieve test, Suspensibility~~ These tests are not applicable for GDs as these formulation type is applied undiluted. Refer to specification template for GD formulations in FAO/WHO Manual. Tablets: Degree of dissolution and solution stability* MT ~~179~~ 179.1 New MT version adopted by CIPAC.

	Ultra Low Volume Liquid: Viscosity MT ~~22~~ 192 Wrong viscosity method. Water-Dispersible and Water-Soluble Granules: Flowability MT ~~172.1~~ 172.2. New MT version adopted by CIPAC.
Appendix 3	Insert organisms definition to align with ACVMs 2016 Guidance document Microbial Agricultural Chemicals[4]. Nematodes are not in the scope of ACVM (see microbial agricultural chemicals). Also, in section 6, the document excludes Microbials from this guidance document. Delete *"Organisms (including, ….)"*.
Home garden products	This section provides feedback on crop protection products registered solely for home garden uses: Applying the same standards to low risk products, such as those supplied solely to the home gardeners, is viewed as an unnecessary drain on ACVM's limited resources for no improvement in risk management. ACVM have previously stated their only concern – and indeed the only part of the ACVM Act relevant to home garden products – is potential contamination or exceedance of MRLs for domestically traded produce but due to the low volume of such produce where these products may have been used (relative to that sold domestically, that is not organic) is exceedingly small then the risks to manage is also exceedingly low. The amount of data should be proportionate to the risk – i.e. home garden products for spot spraying only do not represent the same risks as commercial products. The domestic market for home garden products is exceeding small and increasing costs and complexity of registration will essentially make it prohibitive to sell new and maintain current products in this market. This document is very focused on the manufacturer of commercial crop protection products, which is appropriate, but several of these requirements (if implemented) will put an unnecessary burden on manufacturers and registrants of products solely for home gardeners. It is suggested that a different set of requirements (a sub-set) apply to low-risks products / applications, i.e. home garden products. This strategy is recognised and done by other regulators overseas. There needs to be exceptions or entirely different data requirements. Without change it would almost be impossible and prohibitively costly to introduce a new product into the home garden market. A risk-based system would allow ACVM to focus resources on higher risk (from the perspective of the ACVM Act) products.

6. Conclusions

Agcarm:

- Supports ACVM updating the guideline.
- Takes very seriously, any changes to crop protection product regulation and appreciates the opportunity to provide a submission.

[4] www.mpi.govt.nz/dmsdocument/19484/direct

- Strongly requests this document is re drafted for international alignment to ensure registrants continue to bring new actives and formulations to the NZ market to support the primary sector of NZ. The requirements in this document needs to harmonize with world standards (ie APVMAs chemistry and manufacturing requirements[5]) and provide International continuity. There will be a negative impact on the willingness of crop protection companies to continue to register products in NZ if requirements that are unique to NZ continue to be introduced.
- Requests the opportunity to speak to the points raised in this submission at a workshop once ACVM have considered the submissions.

If NZ wants to achieve the government's goal of doubling our agriculture sector export earnings, while protecting the environment and growing jobs, it must encourage innovation and the registration of new, safer and greener products. We will then all benefit from healthy crops and a healthy country.

The cost of compliance (i.e. specific data generation such as chemistry and manufacturing for NZs small market) are significant and have resulted in decisions not to register new active ingredients and formulation types as well as multiple manufacturing sites. There must be an economic benefit for companies to introduce new products to the NZ market and invest in development of existing ones, and if this benefit is not greater than the barriers to registration, new products will not reach the NZ market. The proposed increases in regulation that are unique to NZ produce a deterrent to register new actives, formulation types and manufacturers (as well as maintain existing ones at registration renewal) to the NZ market.

7. About Agcarm

Agcarm is the peak New Zealand industry association of companies which manufacture, distribute and sell crop protection and animal health products. Our mission is to protect and enhance the health of crops, animals and the environment - through innovation and responsible use of quality products and services.

The crop protection industry is a small robust industry that has a significant impact on our land based sectors. Even a small increase in horticultural productivity has a ripple effect in boosting the economy.

Without crop protection products, it is estimated that New Zealand's economy would lose between $7.5 to $11.4 billion (see NZIER Report – The Importance of Crop Protection Products for the New Zealand Economy at http://agcarm.co.nz/wp-content/uploads/NZIER-Report.pdf)

Not only does the crop protection industry have an important part to play in supporting the economy, it is also vital for producing safe food and protecting our environment. From managing damaging pests and diseases, through to research and disposal, the industry is committed to the responsible use of crop protection products right throughout the product life-cycle.

This stewardship begins at the research and development phase of a product, going on to distribution and use, through the eventual phase-out and disposal of waste.

[5] www.apvma.gov.au/morag_ag/vol_3/part_02_chemistry.php#gen11

We are one of the founders, and a trustee, of the Agrecovery programme which recycles plastic containers and collects surplus agrichemicals. Our members fund the programme by paying a levy on the sale of products.

Ensuring farmers are trained on the most environmentally sound and responsible methods for protecting crops from pests is a priority for the crop protection industry. Our members work with trainers, regulators and growers to achieve the best pest control practices. This ensures we meet the global shared goals of health and safety to people, the environment and the food chain.

We also develop tools to manage biosecurity incursions which damage our native species and crops, along with leading initiatives to protect the health of bees.

Our industry focusses on stewardship and ensuring that there continues to be a variety of new products to offer pest control solutions for growers and farmers. Agrichemicals that are more environmentally-friendly, more effective and more targeted allowing farmers to better control target pests, while protecting human health and allowing beneficial flora and fauna to prosper.

It is a combination of innovation and good plant health that will boost efficiency in farming practices and allow increasingly sustainable food production.