To: Ministry for the Environment
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Submission on:

Hazardous substances assessments: Improving decision-making

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Submitter:

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1. Introduction

1.1 Agcarm welcomes the opportunity to engage with the Government on proposals as outlined in the discussion document 'Hazardous substances assessments: Improving decision-making'. We are supportive of the Governments goals of improving decision-making efficiencies, along with encouraging the registration of new products.

1.2 As per our Vision, Agcarm's strategic focus is on proactive regulatory engagement. We seek improvements in the time, quality and cost for regulatory approval of products, along with legislation that encourages members to develop new and innovative products. This is of high importance to Agcarm members, with regulatory improvements benefiting both the New Zealand economy and environment.

1.3 In relation to the proposals in the discussion document, we have provided in-depth feedback. As the New Zealand voice for the crop protection and animal medicines industries, we encourage the Ministry for the Environment (MfE) to seriously consider our feedback and continue to talk with Agcarm, and our members. Thus ensuring that any proposed policy changes are sensible and workable. In addition, that risk, costs and benefits of any amendments to the HSNO Act are fully considered.

1.4 If further clarification is required on any of our feedback, then please reach out to Agcarm. As per our submission, we are of the opinion that there are further discussions and engagement required prior to taking any of the proposals forward. It is critically important to make changes that work, and this can only be done with government and industry working closely together.

1.5 Industry has appreciated the pro-active approach to the consultation process, and the opportunity provided by the Ministry to discuss the proposals at the two MfE workshops. However, given the importance and complexity of the subject matter we submit that the on-going decision process must not be rushed. As an example, the 2-week period after the MfE workshops to analyse the proposals, consult with members and prepare our submission is viewed as a hasty consultation process. It is in the interests of both the Government and Stakeholders to not rush such important policy proposals.

1.5 In relation to the proposed changes, we offer feedback as below.

2. Recommendations

2.1 Prior to making any further decisions on the 'Trusted Regulator' approach (Option 2) we submit that further discussion is held specifically between the MfE, EPA and industry representatives involved with the registrant process to ensure that the best outcome for all involved parties, i.e. regulators, applicants, industry, New Zealand Inc., is taken forward. Agcarm members would welcome the opportunity to be part of a 'Trusted Regulator' Working Group, and we strongly submit that this is the next stage approach to advance the proposals as outlined in the discussion document.

2.2 Agcarm submit that in the interim (and while the proposed changes are deliberated) that the EPA focus on completing the internal improvements on their approaches to assessments,

thresholds, data sources and decision-making as a more immediate solution to improving their risk assessment processes for hazardous substances.

2.3 Agcarm submits that in relation to the immediate suspension of a substance based on trusted information that the status quo (Option 1) is retained. We do not support the EPA having the statutory ability to suspend or temporarily restrict a hazardous substance immediately without consultation as outlined in Option 3.1.2.

2.4 Agcarm submit that prior to adopting a new classification approach, the EPA should take a number of considerations on board. This would include:

- Considering whether there is new data/information available that has not been considered as part of the primary assessment and would challenge the current classification.
- If yes – then call for a targeted reassessment and specifically request the new information for consideration.
- If no – then consider whether the classification criteria adopted by that regulator follows the same principles adopted in New Zealand. If 'Yes', then complete an internal review to identify why the conclusion differ even though the principles are the same, and if appropriate call for a reassessment under S. 67A of the HSNO Act. If 'No' then no further action would be required.

2.5 Agcarm does not support the proposal to make the 'Call for Information' statutory as proposed in Section 3.2 of the discussion document. Agcarm submits that the current process (Option 1: Status Quo) is retained as per the HSNO Act. As an example, the recent call for information on three neonicotinoid actives resulted in a large amount of information being provided to the EPA by industry. EPA feedback is that the industry already promptly provides the required information when it is requested. Suggestions have been offered as to ideas to improve the current process.

2.6 Agcarm submits in support of companies only involved with the specific substance(s) being targeted by the EPA for provision of reassessment information as outlined in Option 2 of proposal 3.2.2. However, we question how the EPA will know what companies are involved, and how this will be determined. In addition, we recommend that in this instance as the EPA is only modifying the outcomes of something that has already been assessed that a public hearing is not held. In this instance public hearings would be viewed as very time consuming for the EPA and industry, expensive and place unnecessary delays on decision-making.

2.7 Agcarm has received mixed feedback on the proposal for combined process for substances with the same active ingredient – some feedback is in support, but the majority is against. The suggestion is that further discussions are held with Agcarm members, and that in this instance the EPA look at using current legislative requirements under the HSNO Act to achieve their goal. On the positive if the product is for the same use, then this is okay. However, if it is for a different use then a combined process to make decision-making quicker may actually end up with the EPA imposing some controls which result in making some products with the same active ingredient unusable.

2.8 The discussion document gives the impression that Data Protection is resolved and the status quo is appropriate. EPA currently relies on the ACVM Act to grant data protection to data/information provided to support new substances in NZ. The ACVM Act covers only products used in the context of food production. Products used in forestry and urban pest control, for example, are not in the scope of Data Protection under the ACVM Act. Without data protection under the HSNO Act there is little incentive to develop less harmful substances that could be used in these sectors. This is because the day after an approval is granted by the EPA the market would be open for generic companies to bring their own brands to the market without the provision of data/information to the EPA. Hence, Agcarm

submit that any future changes in the HSNO Act must include the provision of Data Protection as per requirements contained within the ACVM Act.

2.9 If the proposal related to older substances being given the same controls as recently approved substances that contain the same active ingredients is taken forward, Agcarm submit that this should be done without excessive burden under section 67A of the HSNO Act. Given the need for further discussions, we favour Option 2: Combined Process. The alteration is viewed as minor in effect, as the discussion and deliberations have already been covered via the most recent assessment. In addition, we submit that a Cost Benefit analysis is carried out, that looks at the potential consequences to such a decision. Both economically and environmentally.

2.10 Agcarm recommend that the MfE take on board the comments on the EPA performance. We encourage the Ministry to take heed of our feedback within this submission, listen to industry and include Agcarm and our members in on-going discussions to ensure that any new proposals to improve decision-making are actually workable.

2.11 When it comes to new tools to improve decision-making we encourage to Ministry to take note of the Regulatory Assessment Software as outlined in Section 5, and its capacity to reduce burden on the regulator and increase efficiency and effectiveness.

3. Specific Comments on the Proposals

Feedback is provided on the main Ministry for the Environment proposals as outlined below.

3.1 Use of International Information via Trusted Regulators

3.1.1 Agcarm has a mixed view with the proposal of taking the 'Trusted Regulator' (Option 2) approach. We understand the intention of the Ministry to make better use of overseas regulators data to improve New Zealand decision-making processes. However, we share concerns as to how a Trusted Regulator would be selected, how the EPA will interpret the data into their decision-making, whether this approach is a realistic from a wider New Zealand perspective, and how this would affect the status of the New Zealand EPA internationally.

3.1.2 As per Option 2c as a means of improving decision-making we can see some value in the EPA making better use of overseas reviews in order to improve the efficiency, consistency and quality of their assessments. However, there must always be a New Zealand specific assessment. Reviews by overseas regulators should be used to inform and validate decisions around hazard assessments (toxicological end-points), but should not be used as a substitute for the EPA carrying out its own evaluation of all the data and providing a science-based risk assessment. New Zealand's unique environment, economy, protection objectives and culture mean that it is not appropriate to superimpose an overseas regulator's risk assessment onto New Zealand.

3.1.3 As with the Option 2 proposal it has been noted by Agcarm members that some of the trusted regulator concepts are already practiced by the EPA in its current procedures. For this reason it is seen that the proposals in the discussion document will do little to improve EPA efficiencies, but there is benefit in formalising the current practice of the EPA and communicating this to stakeholders to improve transparency.

3.1.4 Prior to making any further decisions on the 'Trusted Regulator' approach we submit that further discussion is held specifically between the MfE, EPA and industry representatives involved with the registrant process to ensure that the best outcome for all involved parties, i.e. regulators, applicants, industry, New Zealand Inc., is taken forward. Further

discussions are needed to determine technical details, the scope of information to be used, and the extent in which is can be relied upon.

3.1.5 Agcarm members would welcome the opportunity to be part of a 'Trusted Regulator' Working Group, and we strongly submit that this is the next stage approach to advance the proposals as outlined in the discussion document.

3.1.6 Agcarm also submit that in the interim (and while the proposed changes are deliberated) the EPA continue with the planned announced internal improvements on their approaches to assessments, thresholds, data sources and decision-making as a more immediate solution to improving their risk assessment processes for hazardous substances.

Reasoning

I. When compared to other countries, feedback received from overseas applicants and regulators have rated New Zealand as a respected and trusted regulator internationally. Senior management within the EPA has been indicating for a number of years that changes to their internal assessment processes are forthcoming, and that these changes would make the New Zealand EPA one of the world's leading regulators, i.e. lift the status quo.

II. Hence, the proposal to make use of other countries regulator's data is contradictory to the NZ EPA's goal of their 'leading regulator approach'. By taking the proposal forward of using a 'trusted regulator's information from another country during assessments and reassessments, then we would become a follower and not a leader.

III. From an industry perspective we see greater benefits in the EPA focussing on improving their internal systems, resourcing, technical expertise and implementing the various improvements that they have indicated to industry, prior to considering making better use of overseas data. If the internal improvements at the EPA are made in the near future to improve application processing, then we would support further discussion on the 'Trusted Regulator' approach.

IV. Feedback from some Agcarm members indicates that the NZ EPA may on occasions apply different approaches when compared to overseas regulators assessment processes. This includes differing interpretation of data, sources of data not aligned and the use of differing thresholds for hazard classifications.

V. As an example this is currently occurring with substances that have specific hazards in NZ, but for the same substance registered in Australia the hazards do not exist. If a submitter uses a decision from Australia, which was based on different hazard classification of toxicological end points to the NZ data, then a situation could arise where the two identical substances could have very different hazards, approval conditions and use restrictions.

VI. Different regulators have different frameworks for assessment and decision making. While the discussion document failed to make mention of it, the HSNO act states all persons exercising duties under the act must consider economic benefits and costs of using a substance. Other regulators may not have the same mandate, i.e. some have hazard based approach with cut-off criteria that do not examine risks v's benefits.

VII. Risks and benefits must be established in the New Zealand context for both approvals and reassessments. Use scenarios in New Zealand may be very different to those overseas, therefore the information from other regulators may not be applicable to the New Zealand situation.

VIII. The discussion document cites saving time and resources for both the regulator and the industry. It is unclear that there would be a material benefit to either party. In those

instances where New Zealand is an early entry country for new compounds, there could be no other regulator assessments or decisions for the EPA to rely on, and the applicant would still need to complete an application detailing the uses, risks and benefits relevant to the New Zealand situation.

3.2 Immediate Suspension Based on Trusted Information

3.2.1 Agcarm submits that the status quo is retained. We do not support the EPA having the statutory ability to suspend or temporarily restrict a hazardous substance immediately without consultation as outlined in Option 3.1.2.

3.2.2 The proposal as outlined in Option 3.1.2 would give too much power to the individual decision-maker(s) within the EPA. There is the potential that decisions will be made by an individual at the regulator that are not evidence based, which goes against the purpose of the HSNO Act and/or that decision criteria will be applied subjectively, not objectively or consistently. Any decision to suspend or temporarily restrict a hazardous substance must follow a set process, which includes consultation with industry.

3.2.3 The proposed changes could have the potential to be very disruptive to the market, along with the environment should a substance be suddenly blocked based solely on overseas decisions, which may be biased and politically motivated (as experienced in the European Union, for example).

3.2.4 Hence our support for Option 1: Status Quo to be retained, with a caveat that in the future the EPA specifically indicate what information is necessary to address the risk that has been identified.

Reasoning

I. The discussion document indicates that the proposed change in decision-making protocol would reduce time and resources for collecting information while the assessment is underway. See quote from the discussion document *'the assumption is that the industry would be more motivated to give information to maintain the existing approval after the EPA has taken this action'.* This is not what the EPA has reported as the outcomes of current and on-going reassessments, where the industry already promptly provides additional information to the EPA on request.

II. If the intent of the proposal is to speed up the reassessment phase, it would be more appropriate for the EPA to specifically indicate what information is necessary to address the risk that has been identified.

III. As a real example where immediate decision-making would be dangerous is where more than one product can use the same approval, i.e., approvals are not product specific. In this situation the EPA may decide to suspend an approval based on one product that would inadvertently affect all products, even if they are still acceptable.

IV. Based on some Agcarm member prior experiences, industry considers that improvements could be made in several areas as a means to avoid decisions resulting in different outcomes for substances of a similar nature, the communications of actual decisions, and the process for making decisions. This proposed change could lead to greater uncertainty for industry, place the wider New Zealand economy and environment at risk, and is seen as providing no benefits. Questions also arise as to how it would be managed at the various levels, such as manufacturer, retailer and user.

v. Given the information provided in the discussion document it is unclear what risk this proposal is managing. The specific example in the discussion document of organophosphates and carbamates is counter -intuitive. It suggests that these substances posed an immediate risk to the environment and human health and thus warrant immediate restrictions, yet when the EPA reassessed them they ended up renewing many of the approvals. Temporarily restricting these substances would not have made sense in this context.

vi. If there are to be changes to Section 64 of the HSNO Act the actual problem should be articulated in a clearer way. How many substances are the EPA and the Ministry for the Environment aware of where there is an immediate need to revoke approvals? If there are examples where this needs to happen is the current wording of section 64 of the HSNO Act an actual impediment to achieve this? Are there other legal options that could be considered such as the "Red Alerts" the EPA has been issuing on certain substances, or restrictions under the ACVM or WorkSafe regulations?

3.3 Hazard Classification changes based on a trusted regulator's decision

3.3.1 Agcarm submit that prior to adopting a new classification approach as proposed in Section 3.1.3, the EPA should take a number of considerations on board. This would include:

- Considering whether there is new data/information available that has not been considered as part of the primary assessment and would challenge the current classification.
- If yes – then call for a targeted reassessment and specifically request the new information for consideration.
- If no – then consider whether the classification criteria adopted by that regulator follows the same principles adopted in New Zealand. If 'Yes', then complete an internal review to identify why the conclusion differ even though the principles are the same, and if appropriate call for a reassessment under S. 67A of the HSNO Act. If 'No' then no further action would be required.

3.3.2 In consideration of the above approach and dependant on further discussions on the 'Trusted Regulator' proposals as per Section 3.1 in this submission, Agcarm submit that Option 3*: Adopting a trusted regulator's decision following an controls updating process,* would be the most favoured of the three options to explore in greater detail.

3.3.3 Despite GHS being forced to be adopted globally, there is in fact no harmonization of hazard classification / poison scheduling globally. It is common for the same active to have different warning statements to be adopted as appropriate in AU, US and EU as they do depend on the legislative framework of each particular country. Each overseas trusted regulator has its own system and relying on the decision made by only one, "preferred" has no justification. For HSNO to be correctly assigned, a proper risk assessment of underlying data must be performed as opposed to a blunt transfer of hazard statement from an overseas jurisdiction

3.3.4 The EPA should be continually reviewing new information from overseas regulators about the hazard classification of hazardous substances and determining if there is a scientific basis for any changes made in other jurisdictions. Should there be a need for a change, based on sound scientific evidence, then this should be done in a timely manner.

3.4 Reassessments – 'Call for Information' being made statutory

3.4.1 Agcarm does not support the proposal to make the 'Call for Information' statutory as proposed in Section 3.2 of the discussion document.

3.4.2 The document implies that the EPA is not receiving good quality information in response to its call for information requests. The EPA does, however, generally receive large amounts of studies and information in response to such calls for information. At times information may be withheld due to a lack of data protection assurances (see Section 4.2).

3.4.2 Agcarm submits that the current process is retained (Option 1: Status Quo) as under the HSNO Act. Suggestions are offered as to how to improve the current processes.

Reasoning

I. Feedback from Agcarm members on the 'Call for Information' process, indicates that they are very committed to providing information when requested by the EPA, for example, the recent call for information on three neonicotinoid actives resulted in a large amount of information being provided to the EPA by industry. This would align with the comments made in Section 32 (i) where the EPA feedback is that the industry already promptly provides the required information when it is requested.

II. If in the case of a company not submitting information, then it is to their loss. They will have to accept the EPA decisions, and will have no influence over the outcomes.

III. A question arises as to how the EPA will police that all relative companies/industry groups have provided information? In hindsight, the EPA would not have the market intelligence to effectively enforce making the 'Call for Information' statutory. In fact, it would be a resource draining for the EPA to carry out required compliance actions when there is not a problem to address. Internal resources would be better assigned to progressing applications and improving other EPA systems.

IV. The current process for Call for Information of on-going risk reassessments is considered too broad in scope, and does not specify what data gaps are to be considered. A more targeted approach would allow the EPA to focus on issues that are relevant under the EPA's risk assessment framework and would ensure the information that is necessary for the reassessment to progress is provided.

V. Given the general lack of clarity about what information the EPA requires, mandating industry to provide information is unlikely to be helpful. It is also difficult to see how this would operate in practice, given that there can be many importers and manufactures of the same hazardous substance and not all will be known to the EPA. The document states that data protection has been considered and that "*the current HSNO data protection mechanism is appropriate to manage hazardous substances in New Zealand*". It is unclear what this statement is based on, or how this conclusion was reached. For HSNO reassessments there is typically no data protection, so information provided by one importer or manufacturer would presumably be freely used by the EPA to the benefit of all products containing the same active ingredient.

VI. There seems to be no acknowledgement that providing studies and technical support for reassessments has a cost associated with it which may not be equally spread among importers and manufacturers. Generally speaking, product manufacturers will provide all the data they have available to defend their products in a review, however where a data call in goes beyond providing studies to address specific topics, clear guidance on the type of data required and expected will go a long way to improve the quality of the data set obtained.

Suggested Improvements to current process

VII. Agcarm views the current problems with the EPA 'Calling for Information' is that this is carried out at a stage where the scope of the reassessment has not been established.

VIII. Rather than change the legislation, the process under pinning the reassessment programme should be targeted and focussed on addressing risks that have not been considered in previous assessments, but that are relevant under the current risk assessment framework. This could involve a report by the EPA specifically addressing what are the risks that were not considered part of the previous assessments, and what are the data gaps.

IX. The report would then be the driver for the whole process, and there would no need for a 'Call for Information' at this stage as the EPA would be establishing grounds for reassessment and subsequently requesting the information required to address data gaps/risks as part of the reassessment process.

Looking at this in a simple way, the EPA reports the risks and data gaps:

- If new risks, but no data gaps – set grounds/ re-do the risk assessment/ publically notify outcome/ publish data
- If new risks and data gaps exist – set grounds/ publically notify the new risks and data gaps/ re-do risk assessment based on new data
  - All bases covered – publically notify outcome/ publish decision
  - Lack of information –to address the problems – consider risk/ benefits analysis and additional controls/ safety factors feasibility – publish decision.

X. A further consideration would be for the EPA to have greater communication with the ACVM team at MPI on label approvals, for example, when checking the compliance of relevant HSNO statements.

XI. As per the data protection recommendations, the MfE needs to introduce data protection into the HSNO Act, as this will further encourage applicants to provide information in a secure environment, where competitor cannot access their data.

3.5 Targeted consultation for modified reassessments

3.5.1 Agcarm submits in support of companies only involved with the specific substance(s) being targeted by the EPA for provision of reassessment information, as outlined in Option 2 of proposal 3.2.2. However, we question how the EPA will know what companies are involved, and how this will be determined.

3.5.2 In addition, we recommend that in this instance as the EPA is only modifying the outcomes of something that has already been assessed that a public hearing is not held. In this instance public hearings would be viewed as very time consuming for the EPA and industry, expensive and place unnecessary delays on decision-making.

3.5.3 An alternative recommendation is that the EPA could publically notify the modified reassessment via the NZ Gazette, and thus allow for written submission from the general public.

3.5.4 The issue with reassessments is that Section 63c of the HSNO Act does not distinguish a reassessment targeting the provision of data/information to support a literal reassessment of the substance from a request by the applicant, e.g. new uses, change in application rates.

3.5.5 Requests from the applicant should be considered as variations to the current approval and processed without the need of a public hearing as these are substances already approved for use in NZ. A notification in the NZ Gazette would suffice in this context.

- All reassessment should be de facto modified assessment as there is an expectation that the EPA has identified a risk and a data gap that required the substance to be re-assessed.
  In such cases, it seems appropriate to ensure the message reaches out to all the companies involved in the process and in addition to a public notification in the NZ Gazette the EPA should also hold a targeted consultation.

3.5.6 The issue here is that the EPA regulates substances as it does not hold a register of all companies commercialising these substances in NZ. To ensure such traceability, the EPA would have to change the scope of the Act from substances to Trade Name Products.

3.6 Avoiding Duplication when Reassessing Priority Chemicals

3.6.1 Agcarm submits in support of the Status Quo (Option 1) being retained as outlined in proposal 3.3.1.

3.6.2 The Priority Chemical List (PCL) has been created based on a very simplistic hazard model and without true risk assessment. For example, there is at least one chemical that was put there just after approval was given by the EPA where all currently available data had been assessed. Hence, there is no new information and no need for re-assessment. In the interim, the same information as provided to EPA was re-assessed by another trusted regulator who found out that a lower hazard classification should be applied as previously assessed. Despite the lower classification, the EPA would not engage in discussions as to reassessing its decision and removing the chemical from the PCL. Based on this example the shortcomings of the PCL are highlighted as to how it was developed and how it is maintained.

3.6.3 Agcarm submit that the EPA should continue to proceed through a normal rigorous process of demonstrating the reasonable grounds for re-assessment first before embarking on a lengthy and costly journey which may otherwise be completely unjustified, unnecessary and arbitrary.

3.7 Combined process for substances with the same active ingredient

3.7.1 Agcarm has received mixed feedback on this proposal 3.3.2 (Option 2) – some feedback is in support, but the majority is opposed. The suggestion is that further discussions are held with Agcarm members, and that in this instance the EPA look at using current legislative requirements under the HSNO Act to achieve their goal.

3.7.2 On the positive if the product is for the same use, then this is okay. However, if it is for a different use then a combined process to make decision-making quicker may actually end up with the EPA imposing some controls which result in making some products with the same active ingredient unusable. This is unfeasible for both the EPA and industry. Both would have to always be prepared for reassessments triggered by just one applicant.

3.7.3 As an Example: The EPA receives an application for a new glyphosate formulation. Unlike for existing glyphosate formulations, they now want to impose buffer zones on this new substance. All existing approvals will be reassessed at the same time to apply buffer zones across the board (not necessarily the same buffer zones but a consistent spray drift policy.

3.7.4 On the second point in such cases the EPA would be viewed as interfering with the free market. The new substance would cause no harm beyond the products that are already available in the market. Also, there is an expectation that the substance will be approved under the current principles and risk assessment framework adopted by the EPA. As such, it is unlikely the risks (if any) that will rise from the use of the substance will be unacceptable.

3.7.5 The EPA should have mechanisms to ensure the outcomes of a reassessment are directly transferable to all substances that fit under the scope of the reassessment. This can be done by imposing a condition in the approval saying that when the reassessment X is completed the controls and conditions would be aligned with the outcomes of the reassessment.

3.7.6 One of the mechanisms currently available in the HSNO Act to make such amendments without excessive burden is triggering such reassessment under section 67A (minor or technical amendments to approvals).This is because in fact the alteration is minor in effect, as the whole discussion has been already covered by the reassessment process.

3.8 Updating controls of existing substances

3.8.1 As with Section 3.6, there are pros and cons with the proposal related to older substances being given the same controls as recently approved substances that contain the same active ingredients. We favour Option 2: Combined Process, with the recommendation that further discussions are held with industry.

3.8.3 There is potential for this to solve a lot of the barriers to introducing new substances by ensuring a level playing field. But, it is possible that inadvertently the marketplace would become even more fragmented and complex with approvals changing constantly because the EPA decides to implement a new ‘best practice’ that is then applied to all products in the marketplace.

3.8.4 If this became a regular occurrence, it would place a large cost on industry, with fewer new products introduced. If the EPA is prepared to commit to a standard for their decisions and controls and ensure that this standard is only changed every 10 years (for example) this may work.

3.8.5 If this proposal is taken forward, Agcarm submit that this could be done without excessive burden under section 67A of the HSNO Act. The alteration is viewed as minor in effect, as the discussion and deliberations have already been covered via the most recent assessment.

3.8.6 In addition, we submit that a Cost Benefit analysis is carried out, that looks at the potential consequences to such a decision. Both economically and environmentally.

4. General Comments relative to the Discussion Document and Proposals

4.3 General comment in regards to the EPA

4.3.1 Acknowledging the narrow scope of the current proposal, *"limited to applying a 'trusted regulator' approach*", as well as complexity of the proposed solutions, it is the opinion of the industry that there are some other parts of the current legislative framework which could be re-written to make it easier for the regulator to achieve the desired policy objectives of incentivising the introduction of beneficial, more efficient and safer chemicals, and the appropriate management of chemicals in New Zealand. The industry is ready and willing to collaborate closely with MfE and EPA in order to achieve the best possible outcome for all stakeholders, for the environment and for New Zealanders.

4.3.2 The EPA reference the fact that ACVM recognises APVMA data/decisions. This is regarded as duplicitous because the ACVM and APVMA have almost identical data requirements. The source of the data for them is generally the same and they are less subjective, more objective when assessing the data.

4.3.3 The EPA vs other regulators is almost the opposite. The EPA are known to source their toxicological data from a variety of sources where data quality is variable and interpretation is not consistent. This leads to inconsistent decisions, which clearly causes issues if some decisions are based on overseas decisions/data and others are based on EPA data.

4.3.4 Industry regards that the EPA is in this position because over the prior 10 years they have constantly added additional steps, data requirements, models and processes to their registration approvals. This has created a system that is viewed as inefficient, hence the drive by the MfE to improve efficiencies via the outlined proposals. At times there has been little consultation with industry, with feedback when requested, generally ignored. The EPA are now finding that they don't have the resources to fulfil their role. Ignoring feedback from industry only worsens these problems.

4.3.5 The first priority should be better communications between the EPA and stakeholders and greater transparency about the EPA's processes. Suggestions about how to start this include:

- Publication of the EPA's approach to application pathway assessments and how this links to the reassessment program.
- Communication of the intended schedule for reassessments with some indicative dates of when stakeholder input will be required.
- More clarity from the EPA about exactly what information they require for the call for information. Prior engagement with key stakeholders would be beneficial.

4.3.6 The irony is when the HSNO Act was first implemented there were many warnings by industry that it would create a situation that we are currently facing – high cost, inconsistent controls in the marketplace, impractical decisions, and inefficiency. When ERMA first started operating they were pragmatic, efficient and approachable but over time this has been degraded by subsequent policy changes.

4.3.7 Hence, we encourage the Ministry for the Environment to take heed of our feedback in this submission, listen to industry and include Agcarm and our members in on-going discussions to ensure that any new proposals are workable.

4.4. Other Comments

4.4.1 The lack of discussion of *Māori* /iwi issues in the document is worthy of comment given the concerns raised by iwi over the past few years.

4.4.2 The current Priority Chemical List (PCL) for reassessment is dominated by plant protection products. Hazardous substances approved under group standards are largely excluded from the current reassessment regime. There is no scientific or risk based reason for this.

4.4.3 In many cases group standard approvals offer a better potential to use international regulator assessments due to the similar exposure and risk profiles between New Zealand and other countries. There are already good examples of the EPA using such approaches for cosmetic products (based on European regulation) and for surface coatings standard (based on Australian standards). Similar approaches could be applied for other types of hazardous substances.

5. Regulatory Assessment Software - A tool supported by Agcarm to improve Regulatory Assessment Efficiencies

On discussions with MfE officials, other proposals for improving decision-making have been requested. Based on this request, Agcarm is in support of the MfE assessing the Regulatory Assessment Software and its capacity to reduce burden on the regulator, and to increase efficiency and effectiveness. Details on the tool are provided as below.

Regulatory Assessment Software

Agcarm are in support of the MfE assessing expert systems that have the capacity to reduce burden on the regulator and increase efficiency and effectiveness. One such regulatory assessment tool is PERAMNZ. This tool has been developed as a fully integrated rapid assessment tool and would provide a number of benefits that would warrant further evaluation by EPA.

This regulatory assessment tool (PERAMNZ) can be instrumental in minimising the regulatory effort required to assess new substances and those undergoing reassessment. Its use and application are directly relevant to many of the options for change proposed in the consultation document. As such, further evaluation by EPA of this tool is recommended.

However, as with the use of any such systems, the EPA first needs to clearly publish its risk assessment methodology so that is applied in a consistent and predictable manner. It would then be possible to fine-tune a system such as PERAMNZ so that it delivers the efficiencies and predictability sought by EPA and registrants to support the decision-making process.

In addition, there are several other benefits. The availability of this regulatory tool will allow the EPA to meet the challenges of “doing more with less” while facilitating improvements in scientific robustness, increased complexity in risk assessments, while at the same time, greatly increasing efficiency in assessment. It will enable the EPA to maintain rigour in the assessment process while better managing its ability to meet statutory timeframes.

6. 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.

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.

APPENDIX 1: Agcarm Membership

Agcarm Membership

Agcarm represents around 90 percent of the crop protection, animal medicines and rural retailers industries within New Zealand. Our companies are both local and globally linked, producing products that enable our farmers and growers to supply high-quality food and fibre into domestic and international markets, along with keeping our animals and pets healthy.

Animal Health Manufacturers

- Bayer Animal Health
- Boehringer Ingleheim
- Donaghys
- Ravensdown
- Elanco Animal Health
- MSD Animal Health
- Zoetis NZ
- Troy Animal Medicines

Crop Protection Manufacturers

- ADAMA New Zealand
- AgriNova NZ Ltd (trading as Grochem)
- BASF New Zealand
- Bayer CropScience
- Donaghys
- Corteva
- FMC
- UPL
- Key Industries
- Ravensdown
- Nufarm
- Syngenta Crop Protection
- Lonza
- Kiwicare

Distributors

- Ashburton Trading Society
- Farmlands Co-operative
- Horticentre
- ICD Group
- New Zealand Farm Source
- PGG Wrightson Ltd
- Venture Exports
- Hodder and Turner

Corporate Associates

- AgriMedia
- Argenta
- Eurofins Agrosciences Services
- Medicines New Zealand
- Peracto New Zealand
- Philstic Labels
- Rural Contractors
- Sumitomo Chemical

- Rainbow chemicals

Individual Associates

- Hill Laboratories
- RxVet Limited
- Mantissa Corporation
- Agworld
- Ag Services
- NZ Apple and Pears
- Market Access Solutionz
- Renovo Technologies
- NZ Sports Turf Institute
- Molloy Agricultural Spraying
- Intuit Animal Health Consultants
- Zespri
- HortNZ
- Tracta
- IPPC
- BNS Agchem
- Redcap solutions
- De Groot
- Ranfurly Orchard Services
- NZKGI
- BioGro
- FieldTek
- On Regulatory
- De Sangosse
- Educhem


AGCARM
Healthy crops : Healthy animals : Healthy business