To: Environment Select Committee
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Submission on: Hazardous Substances and New Organisms (Hazardous Substances Assessments) Amendment Bill

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1. Introduction

1.1 Agcarm welcomes the opportunity to submit on the proposed bill. Agcarm's primary focus is on how the proposed changes to the way hazardous substances are assessed, will affect applications for crop protection products and veterinary medicines.

1.2 Overall, we are supportive of the intent of the bill, i.e. improving how the EPA makes decisions, however we do not think that the proposals in the bill will achieve this. Accordingly, in addition to feedback on the proposals in the bill, we also propose a series of recommended changes to the HSNO Act which will prove more effective than the current bill in terms of improving the efficiency of the EPA's decision-making, and safeguarding people and the environment.

1.3 Our involvement throughout the MfE consultation process has enabled Agcarm to contribute to the policy considerations around the proposals. However, now that there is more clarity as to what specific changes to the Act are proposed, we are in a position to provide further feedback. This is provided below.

1.4 Agcarm wish to be heard by the Environment Select Committee and seek the opportunity for an oral presentation.

2. The Status Quo – Overseas Information

2.1 The Hazardous Substances and New Organisms (Hazardous Substances Assessments) Amendment Bill aims to enable the EPA to make better use of relevant information from international regulators. It is important therefore to understand how the EPA currently uses information from overseas regulators when assessing hazardous substances.

2.2 The consultation document and Regulatory Impact Analysis from MfE as well as the press releases from the EPA and MfE give the impression that currently the EPA barely makes use of information from overseas regulators. This is not the case.

2.2 Overseas information is frequently used by the EPA when it assesses hazardous substances. This is more common when an application is either a reassessment or includes a new active ingredient that has been approved elsewhere in the world, however it also happens sometimes when an application involves existing active ingredients only.

2.3 The EPA uses information from overseas regulators in two main ways when assessing hazardous substance applications. The first is that technical information and modelling conclusions from other regulators inform the EPA's own technical assessments and risk modelling. The second is that the approval status of active substances in overseas jurisdictions directly informs the decision-making and assessment process. Evidence of both of these can be found in the documents that are published as part of the EPA decision-making process. Alongside the written decision for each application, the EPA usually publish a science memo which contains a more detailed, technical assessment and justification of the conclusions they came to regarding risks associated with an application.

2.3 One such example of the EPA heavily relying on international information is for application number APP203766. This was an application for a substance that contained an active ingredient that was new to NZ. In assessing this application, the EPA considered reports from the European Food Safety Authority (EFSA) and the European Commission (EC). The EPA used these reports to:

- Add weight of evidence in support of the EPA conclusions (See page 72 of the science memo)
- Derive toxicological endpoints used in the risk assessment (See page 7 of the science memo - item 1.8, Page 86 of the Science Memo – Table 52, and page 87 of the science memo – Table 53)
- set impurity limits associated with the substance (See page 87 of the science memo – Table 54)

2.4 Another example is APP203757, which was also an application that contained an active ingredient that was new to NZ. The EPA also relied heavily on data and reports from the EFSA and the EC. In Appendix C of the Science memo, which described the mammalian toxicity/human health risk assessment, all data for the active ingredient was sourced either from the applicant, or from the draft EC assessment report. In appendices D and E, which describe the environmental fate and ecotoxicity of the substance, all data were sourced from either EFSA's conclusions, or the draft EC report. In total, the draft EC report is referred to over 20 times in this assessment, and the EFSA conclusions are referred to almost 100 times.

2.5 A further example is the EPA's reassessment of paraquat (APP203301). In this application, the EPA used data from international regulators to:
- Inform the EPA's conclusions as to which endpoints to use in their modelling (See page 29 of the science memo)
- Derive toxicological endpoints used in the risk assessment (See pages 19-21, Tables 7 and 8, and page 30 – Table 11 of the science memo)
- Inform the decision-makers what the regulatory status of this active ingredient was in overseas jurisdictions (See pages 18-20 of the application form).

2.6 Agcarm is of the view that international information is already extensively used by the EPA and this can be demonstrated in the public documentation from applications. We ask that the Select Committee carefully consider what differences the proposed changes in the Bill would actually bring and whether they will deliver the efficiencies that have been touted. We also ask the committee to consider other options for improving the operation of the HSNO approval/assessment system.

Comments on specific proposals in the Bill

Publication of Decisions

3.1 Section 4 of the bill proposes inserting two new sections into the Act, 20B and 20C. Section 20B relates to how the EPA publishes decisions made under the HSNO Act. Clause (1) will require the EPA to do certain things.

3.2 Clauses (1)(a) and (1)(b) don't appear to change anything procedure-wise but consolidate existing requirements scattered throughout the Act and make clear that these apply to all decisions. Clause (1)(c) however, which requires the EPA to give public notice of the decision as soon as practicable after the decision is made, appears to be a new requirement.

3.3 Currently decisions are uploaded to the EPA website when they are notified to applicants and are then available for the public to view. In terms of public notification, the EPA publishes a monthly newsletter (The HS update) for Hazardous Substances which lists all of the decisions that were made during the previous month. In addition to this, if an application has been publicly notified, then when the decision is released the EPA usually put out a media release.

3.4 Agcarm members want to ensure that the requirements of the proposed section 20B (1)(c) do not result in excessive EPA resources being directed away from processing applications towards publicly notifying decisions. We consider this a possible outcome based on the current wording of the bill in that it requires decisions to be publicly notified as soon as reasonably practicable. We note that the proposed section does not just apply to applications that have been publicly notified in accordance with section 53 (or consulted on under the proposed section 53AA), but presumably applies to all statutory applications.

3.5 To ensure that this new requirement does not become a drain on EPA resources and to provide certainty for the EPA, applicants, other stakeholders and the general public, we recommend that the proposed section 20B (1)(c) be amended to require the EPA to notify to the New Zealand Gazette a list of all issued decisions at regular intervals, such as once every 10 working days or once per month. This notice can then direct readers to the EPA's website just as the current monthly HS update does.

3.6 Agcarm does however recommend that the timeframe of "as soon as practicable" be applied to clause (1)(b), so that the EPA would be required to notify the applicant and any submitters of a decision in a timely manner once it has been made.

3.7 Having the New Zealand Gazette as the primary means of notification would also bring predictability for applicants and stakeholders of knowing where they will find out about HSNO related proceedings.

Reassessments work plan

3.8 The proposed section 20C in the bill will require the EPA to develop and publish a workplan setting out the priorities for the reassessment of hazardous substances. Agcarm members support this initiative. However, in relation to this section we request that EPA-initiated reassessments, whose aim is typically to bring old approvals in line with the current science, are differentiated from externally applied for reassessments, which usually seek a specific amendment to controls to extend use into new situation (e.g. increase the max application rate, which was originally established for one crop and now needs to be increased to allow use in another crop where a higher rate is required to achieve efficacy). It should be made clear that the workplan should only include EPA-initiated reassessments and that any externally applied for reassessments should be processed just like an application for a new approval, as is currently the case.

3.9 At the moment the HSNO Act uses the one term "Reassessment" to describe applications that can vary significantly in scope, from a complete review of an approval with the possibility that it is revoked, to a registrant applying to request a specific variation to the controls of an approval. These applications differ significantly in terms of what they are seeking to achieve and the work required for them by both applicants and the EPA.

3.10 It would be unfair if the EPA were to process externally-generated reassessments by adding them to the reassessment work plan to process. This could delay their assessment by several years. At the moment they are processed as the EPA receives them, just as is done for other applications. This should continue to be the case. This situation can be easily avoided by making it explicit in the new section 20C that the reassessment work plan is only for those reassessments initiated by the EPA, and that reassessments that come from registrants should not be processed by way of inclusion in this list.

3.11 The introduction of the much needed workplan for EPA-initiated reassessments will provide stakeholders with more knowledge about which substances they should expect to be reassessed in the near future. This is a positive development as it has proven difficult for stakeholders in recent years to know what will be reassessed next. The EPA has often prioritised reassessment activity for substances that would not be expected based on the EPA's Priority Chemical List (PCL).

3.12 The EPA developed the PCL in 2018 and updated it in 2020. This involved screening over 1200 substances and scoring each for its risk to human health and the environment before giving each an overall priority rating from A to F. Despite 36 of the 43 substances on the PCL not being part of any announced reassessments, the EPA has regularly directed reassessment efforts towards priority C, D and E substances rather than the priority A and B substances on the PCL itself.

3.13 Clause 2 of the proposed section 20C will require the EPA to consider Part 2 of the Act and the criteria applicable to determining if grounds for reassessment exist when developing the reassessment workplan. This should help ensure that the EPA focus their reassessment efforts on those approvals and substances where there is the greatest risk.

3.14 Clause 3 of the proposed section 20C requires the workplan to include a list of substances and indicative timeframes for when work will commence by the EPA. We recommend that it also require the EPA to indicate what information in particular they are after or what aspects of that substance have caused them to want to reassess it. This will provide stakeholders with a better indication of what the EPA is concerned about, which will allow for the better provision of relevant information to the EPA. If this is not specifically added, then we request that the bill be changed so that it does not consider inclusion of a substance on the Reassessment Workplan as a matter to be considered when assessing whether grounds exist for reassessment. This would then require the EPA to explain in a grounds for reassessment application, why it is that they are reassessing a particular substance.

New Pathway for Rapid Assessment – 28A(2)(ab)

3.15 Clause 5 of the bill introduces a new pathway for rapid assessment under section 28A for applications that are for a substance that has been approved by an international regulator. Agcarm supports the intention of creating an expedited assessment pathway for new active ingredients approved overseas, however we do not think that making a new pathway under the existing rapid assessment section is the best way to do this.

3.16 Agcarm is pleased to see that the bill will insert clause (5), which requires an applicant wanting to use this pathway to provide evidence that they have the right to use the information that was relied upon by the applicable international regulator. However, the wording for this clause needs to be more specific to remove any doubt as to what it is requiring. Under the current wording, it is unclear whether “the application” is referring to the application made to the NZ EPA, or to the international regulator.

3.17 It should be made explicitly clear that any applicant seeking to use this new subsection, must demonstrate that they have the right to use the data that was submitted to the international regulator, as well as to the NZ EPA – i.e. it is their intellectual property in both jurisdictions, or they have the legal right to use the underlying data in both jurisdictions. It needs to also be clear that this is referring to the underlying data that was submitted to the overseas regulator, not just that a summary report of that regulator’s assessment has been published and is publicly available. Tightening this definition will provide registrants with the confidence to support this. This change will reassure registrants that they are protected from other companies trying to register a product in New Zealand when they do not have the right to the data that formed the basis of an approval granted overseas.

3.18 This same restriction/clarification is also recommended for Section 9 of the bill under the new section 63D (8). The same changes noted in 3.17 above should be applied to that restriction also.

3.19 The rapid assessment pathway is meant to only take a maximum of 10 working days for an application to be processed. The bill requires the EPA to not make a rapid assessment under the newly proposed subsection if the EPA considers that the application will have a) significant cultural, economic, environmental, ethical, health, or international effects; or b) significant effects in an area in which the EPA lacks sufficient knowledge or expertise.

3.20 Based on current and past performance, the reality is that there is no way the EPA would be able to make a decision on whether an application under this new section will have relevant significant

effects within that 10-day timeframe. As a result, the EPA are never likely to choose to use this section, making this amendment to section 28A of no practical value.

3.21 Agcarm supports the idea of an expedited pathway for new active ingredients that have been approved by international regulators, however we consider that this should take the form of its own assessment pathway under a newly created section of the Act, rather than being inserted into the existing section for rapid assessments. Most new active ingredients are processed as notified applications, meaning they have a 100 working day statutory processing timeframe – although we note that a) this is seldom met and b) should be extended as discussed later in this submission. There should be a pathway for an expedited assessment that has a timeframe shorter than 100 working days, but not so short as the 10 working days that would apply under section 28A.

3.22 Such a pathway would also be of greater benefit if the choice to apply under it were the applicants rather than the EPA's. Section 28A only says that the EPA **may** make a rapid assessment of an application but having a pathway that applicants can choose to use, with the criteria of what does and does not fit within that pathway set by the Act rather than the EPA, will mean that the pathway is used more often and would better achieve the goal of introducing to NZ new products that have already been assessed by a credible overseas regulator.

Targeted notification and Consultation – 53AA

3.23 Through the proposed section 53AA, the bill allows the EPA to do either targeted or no consultation on modified reassessment applications, depending on whether the EPA considers the application will have significant effects in the same areas as mentioned in section 3.19 of this submission.

3.24 The EPA does not have sufficient knowledge of the industries that use our products, to be able to accurately determine whether an application will have significant effects – something they are required to determine according to sections 53AA (4)(b)(i) and 53AA (4)(b)(ii).

3.25 If the EPA determines that an application will have significant effects, then section 53AA (5) will require the EPA to consult with all persons who they consider are likely to be directly affected by the reassessment. We are not confident that the EPA will be able to accurately identify all persons who are likely to be directly affected.

3.26 This is because there are often multiple different organisations involved in the regulatory, importation/manufacture, marketing and distribution of the products sold by Agcarm members. Additionally, because most approvals under the HSNO Act are not specific to an applicant but can be matched to by several different importers/manufacturers, it is easy for there to be importers that have independently determined that their product matches an existing approval. The EPA will struggle to identify these affected parties.

3.27 Agcarm members support the idea of allowing for a more targeted consultation process than what usually occurs with public notification currently. However, in order to ensure that affected parties are more likely to have an opportunity to inform a modified reassessment, we recommend that some sort of public notification takes place in all instances, even if it is just notification in the NZ Gazette.

Processing related applications at the same time – 59A

3.28 Section 8 of the bill inserts a section 59A which would allow the EPA to delay the processing of an application when they are also processing another application that contains similar/the same active ingredient(s). Based on the previous consultation undertaken by MfE, we understand that the primary purpose of this section is to allow the EPA to halt processing applications containing a particular active ingredient when that active ingredient is being reassessed. **Agcarm opposes this section in its entirety.**

3.29 The current proposal in the bill would result in applications sitting in limbo for an indeterminate period of time for no reason other than the EPA's own processing delays. The EPA is very slow at processing applications, rarely coming close to meeting the statutory timeframes of the Act. This is true both for reassessments and new applications. The best current example of this is the Synthetic Pyrethroid reassessment. It first had a call for information put out by the EPA in 2018 and the EPA have still not lodged the application for reassessment.

3.30 Synthetic pyrethroids are a relatively large group of chemicals. If all applications containing them were prohibited from consideration until the reassessment was finished, it would be an unreasonable level of interference with the market for these products, without proper justification. This reassessment likely won't be finished until 2023 at the earliest given that no application has been lodged. Section 27 (s) of the Commerce Act states that *"No person shall give effect to a provision of a contract, arrangement, or understanding that has the purpose, or has or is likely to have the effect, of substantially lessening competition in a market".* Section 59A would create situations where the EPA does substantially lessen competition in a market for several years while a reassessment occurs or is expected to occur.

3.31 Most new applications to the EPA are for formulations containing existing active ingredients. These are usually for two situations. 1) new products that will compete with existing ones because they are similar in composition but not quite similar enough that they can use the same approval, and 2) applications that are necessary because reformulating the product means that the formulation that a registrant wishes to sell, no longer technically fits the existing approval – even if it is substantively the same product with the same use pattern as far as the active ingredient is concerned. This is often a business decision decided at a global level for multinational companies. This includes situations where a formulation has been changed such that it is less hazardous than the existing one, as well as changes in the concentration of active ingredient in the formulation, but where the end use substance (i.e. diluted solution used by the end user) is no different.

3.32 Refusing to process these applications not only creates problems for supply chains, such as where an international manufacturer has altered their formulation, but it also grossly interferes with the market for these products. We would like to highlight that most reassessments result in approvals being retained with just a different set of controls applicable, so it is not even as if an active being under reassessment means that it is likely that affected approvals are destined to be revoked and the active ingredient banned.

3.33 Most crop protection and veterinary products in NZ require not only approval under the HSNO Act, but also registration with the Agricultural Chemical and Veterinary Medicine (ACVM) Group within MPI. When a reassessment is done by the ACVM group, new applications containing the applicable active ingredient are rightly still processed and approved, with the registrant alerted to the fact a reassessment is ongoing, and that at the end of it their product will be requested to align with the outcomes of that reassessment. Existing rules should remain in place and inform the controls set on a new application, until the new rules from the reassessment have been determined and implemented. No application should be impacted by anticipated future changes, which are not defined and have no timeline for implementation. Agcarm recommends that MfE contact the ACVM group to investigate ACVM's procedures for this further so that the EPA can model their processes on this, with any required changes to the HSNO Act made to enable this.

New modified reassessment pathway – 63D

3.34 The bill proposes adding in section 63D, a new type of modified reassessment which is specifically for aligning the hazard classifications or controls of an existing approval with either those set by international regulators, or those from newer EPA decisions relating to the same active. The EPA already effectively does this through their periodic chemical reviews, which are done under section 63A. It is unclear why this new section is being created or needed.

3.35 This section needs to be considered alongside the proposed section 53AA which allows the EPA to undertake targeted consultation, or no consultation at all if they consider any effects to not be significant. This creates the possibility of the EPA changing hazard classifications or controls on an approval without the registrant or end users knowing about it or having an opportunity to provide information for consideration.

3.36 In the most recent EPA Chemical Review (APP204060) one registrant did just that. The EPA were proposing to adopt hazard classifications for an approval based on a reclassification of the hazards triggered by an active ingredient. However, because there was an opportunity for registrants to submit, it was pointed out to the EPA that specific studies had been conducted on the full formulation itself which demonstrated that these hazard classifications were not triggered and should not be applied. The EPA agreed with this and ultimately chose to not classify the affected approval as they had initially proposed.

3.37 There is a risk that this opportunity for correction would not take place with modified reassessments given the proposed section 53AA. This creates the possibility of the EPA changing hazard classifications or controls on an approval without the registrant or end users knowing about it or having an opportunity to provide information for consideration.

3.38 Section 15 of the bill would delegate the decision-making power for modified reassessments under 63D to the Chief Executive if there is no public notification or consultation required. Currently modified reassessments are considered by members of the EPA HSNO committee. Because the EPA Chief Executive also decides the pathway for reassessment applications and has significant influence over EPA policy for whether to notify an application or not, we consider that such applications should still be considered by a subcommittee of the EPA HSNO Committee as is currently the case for applications under Section 63A.

3.39 The EPA HSNO Committee recently doubled in size from 8 to 16 members so organizing a subcommittee of 3 members should not be too difficult in terms of logistics. This will help ensure that situations of the EPA choosing to make changes to approvals without consulting anyone, are not disproportionately based on the influence of whoever the Chief Executive is at the time of application.

3.40 As mentioned earlier the EPA do not have a very good understanding of the industries in which our members' products are used. We consider that there is a risk of the EPA thinking that changes they are proposing will not have a significant effect, when in actual fact they may. The way that section 63D and 53AA would interact means that a significant change could be imposed on an approval without the opportunity for those who use that approval to provide relevant information for consideration.

3.41 This would be a bad outcome and could be easily mitigated by requiring public notification for all modified reassessments. We propose that this is made the case, rather than the new section 53AA being adopted in its current form.

3.42 Agcarm considers that the current model for periodic chemical reviews is an effective way of making multiple changes to approvals based on new information, which is effectively what the new section 63D proposes to do. The only issue is that these should be done more frequently so that changes can be processed more rapidly, however this is an EPA resourcing and operational matter rather than something that needs to be changed in the Act itself. We note that the most recent chemical review resulted in changes to 123 approvals, so there is probably an opportunity to break them into smaller, more regular groups of approvals.

3.43 We also recommend that the changes suggested for the statement requiring an applicant to demonstrate their right to use the information relied upon by the international regulator (see section 3.17 of this submission) are also applied to subsection 63D (8).

Temporarily restricting approvals – 64A

3.44 The bill changes what the EPA can do in terms of restricting/suspending approvals prior to undertaking a reassessment. It will allow the EPA to restrict approvals rather than just suspend them. We support providing the EPA with more discretion in this regard. We also support this only being an option once grounds for reassessment have been established – as required by the proposed Section 64A (1)(a).

3.45 We do not however support the lower threshold for taking action compared to the existing section 64. The current section 64 which allows the EPA to suspend an approval, requires the EPA to have reasonable cause to believe that the continued use of a substance poses "significant actual or imminent danger to human health or safety or the environment". The new section 64A would lower this to "reasonable cause to believe that there is actual or likely danger to human health or safety or the environment from the use of the substance".

3.46 The threshold should be the same as the existing one for section 64. The EPA could effectively make a substance unusable through restrictive controls, achieving the same purpose as section 64 but with a lower threshold required to take action. Doing this could have a significant adverse effect on end users so it is appropriate that the threshold of risk for taking such action remains significant or imminent harm. Some crop protection products and veterinary medicines have particular timing windows in which production or animal welfare can be severely compromised if a given control option or remedy cannot be used. The effect of a specific product being unavailable at this time can severely compromise the success and/or wellbeing of that crop or herd.

3.47 Agcarm members have been disappointed at the lack of clarity that the EPA or MfE have been able to provide as to which substances or hypothetical situations would be considered to meet the new threshold of "actual or likely danger" that would not meet the existing threshold from section 64 of "significant actual or imminent danger". This is something that should be able to be clearly explained and stakeholders should know what will be considered by the EPA as evidence that the continued use of a substance carries actual or likely danger and so restrictions may be imposed. A definition of actual and likely danger should be provided.

3.48 There should also be clear expectations as to how the EPA will come to a decision as to whether or not this threshold is met. Will this be a quantitative assessment or qualitative? Will a single report of an adverse event be sufficient evidence or will the EPA require a pattern of evidence? Will modelling results that suggest there are risks be enough, or will the EPA need to demonstrate evidence of real world harm or risk?

3.49 In a stakeholder meeting for these proposed changes to the HSNO Act in late 2019, the then acting General Manager of Hazardous Substances and New Organisms (EPA) was asked if the herbicide paraquat would be an example where the EPA would put restrictions in place. This was an ongoing reassessment at the time and whilst the EPA had recently proposed that the approval be retained with limits on the application rate and method, the reassessment was triggered because initial EPA modelling indicated that exposure to workers applying the product exceeded the acceptable level of exposure by 86 times. The acting GM advised that this situation would **not** have been one where the EPA would seek to impose restrictions under the new threshold.

3.50 The example provided by MfE in the consultation paper for this proposal was the reassessment of organophosphate and carbamate insecticides. However, of the four example compounds highlighted in this document, the only one which had its approval immediately revoked after an in-

depth assessment and consideration by the EPA was Benomyl, which was not being sold anymore anyway. The other three active ingredients were given multiple-year-long phase outs or had their approvals retained with additional controls. Either MfE or the EPA should be able to describe to industry what would be captured by this new threshold that isn't by the existing S64 threshold, and the lack of explanation is disconcerting.

3.51 It was highlighted to MfE at the same meeting mentioned above that this example does not demonstrate that there is a need for a lower threshold, only that the EPA took a long time to decide to reassess those compounds. When an in-depth consideration of the risks and benefits of a substance concludes that it should be retained (for at least several years), you should not treat that as an example where there was a need for the EPA to set restrictions by demonstrating a lower level of risk than under the current section 64.

3.52 The proposed section 64A also does not differentiate between use and misuse. Restricting or suspending an approval should only be done on the basis of there being high risks resulting from use that complies with the existing HSNO controls, ACVM conditions and requirements set by the Health and Safety at Work Act and its regulations. It should also only be use that is consistent with the applicable standard that would be expected for a given product. For example, with NZS8409: Management of Agrichemicals.

3.53 The current wording would allow for the EPA to use incidents of non-compliance or incompetence by the user as reason to restrict an approval. This should not be the case. Such situations obviously present an actual or likely risk, but this is not a reason to restrict how these substances can be used by those who do follow the rules. This can be avoided by applying stricter criteria and qualifying statements in this section around what is meant by "use".

3.54 The proposed section would require the EPA to consult with persons who the authority considers are likely to be directly affected by the restriction of use before setting any restrictions. As mentioned earlier, the EPA will not necessarily know who all these parties are. The EPA should be required to notify their intention to impose restrictions, so that affected parties who the EPA have not consulted with have an opportunity to inform the EPA's consideration.

3.55 Whilst it should apply all the time regardless, we recommend that the EPA be explicitly required to take into account Part 2 of the Act before making a decision to set restrictions. This bill already requires the EPA to do this when developing the reassessment workplan and they should consider these same matters here too.

4. Other suggestions for changes to the HSNO Act and feedback

4.1 Agcarm members are of the view that while the intention behind this bill is good, most of the provisions in it will either do little to improve the way hazardous substances are assessed, or will introduce the risk that inappropriate assessments or decisions occur.

4.2 Agcarm members work with the HSNO Act on a day-to-day basis and some have done so since the Act first became law in 1996. Our members also include many staff who previously have worked at either the EPA or ACVM and understand the regulatory processes and history better than any other sector. Accordingly, we would like to highlight ideas for inclusion that will do more to improve the way decisions are made under HSNO than the bill currently does. We also highlight some of our concerns relating to decision-making.

Data Protection

4.3 Part 6 of the ACVM Act provides registrants with a protected period during which information they submit to the ACVM group for innovative products, is for the registrant's exclusive use. This means

that any competitors who want to copy that registrants product, must either produce their own data or wait for the protected period to expire, before submitting an application for registration.

4.4 While the EPA has in the past said that they honour any data protection conveyed under the ACVM Act, there are currently no such data protection provisions under HSNO. Because the ACVM Act only requires products that are used in food production settings to be registered, many crop protection products will not be granted any data protection status. This means that there is almost no incentive for a company to introduce novel products in sectors that do not produce food such as forestry, plant nurseries, urban pest control, management of water bodies and ornamental plants. This is because a competitor could come along, copying their formulation, and be granted an approval from the EPA based on the study data that the original registrant produced. Generating this data is an expensive undertaking.

4.5 Adding data protection provisions to the HSNO Act similar to those in Part 6 of the ACVM Act will be a strong incentive to encourage innovation and the introduction of new, usually safer, alternatives that are currently available overseas but not in NZ. Adding data protection provisions will also assist with our international obligations as Agcarm understands that in trade discussions with the EU, the EU has proposed extending the protected period for veterinary medicines and crop protection products. The current proposed extensions would be aligning our current ACVM protected periods for veterinary medicines with theirs (an increase of 5 years) and increasing the period for crop protection products in NZ by either 3 or 5 years.

4.6 Agcarm also understands that the CPTPP requires parties to provide 10 years of data protection for new agricultural chemicals[1]. While the ACVM Act was recently amended to increase the data protection period to 10 years for agricultural compounds that are required to be registered, there is still no data protection provision in place for products that do not require registration. Products intended for use in forestry, nurseries and other non-food uses still meet the definition of an agricultural compound under the ACVM Act but do not need to be registered. This leaves some products without that protection despite us agreeing to have this in place under the CPTPP agreement.

4.7 Amending the HSNO Act to include data protection provisions will help NZ to meet its international obligations and will do more to incentivise innovation and the introduction of new products than the current Bill would. Agcarm has advocated for adding specific data protection into the HSNO Act for a long time, and now that a bill amending the Act is before select committee, we again ask that this is added.

Trials and containment approvals

4.8 Until 2016 New Zealand had a system for small scale trial work on substances that was flexible and consistent with what is done in most other parts of the world. These are containment approvals issued under section 31 of the HSNO Act. The EPA previously issued approvals which would allow a company to import and trial in containment, small quantities of any substance they wished to so long as the substance only triggered certain hazard classifications and matched the definition of an experimental plant protection product. These were issued with a standard set of controls such as limits on the total quantity of any substance over the lifetime of the approval (5 years), signage requirements, record keeping and tracking requirements, adverse events reporting and restrictions that ensured substances were only used for the purpose of conducting trials, so could not be sold for example.

[1] https://www.mfat.govt.nz/vn/trade/free-trade-agreements/free-trade-agreements-in-force/comprehensive-and-progressive-agreement-for-trans-pacific-partnership-cptpp/understanding-cptpp/intellectual-property/#bookmark8

4.9 This was changed in late 2016 so that registrants were required to specify which substances and specific formulations they wished to trial at the time of application, rather than be granted an approval to import any eligible substance. The result of this is that multiple containment approvals are granted to any one registrant, with each approval often having slightly different controls even though the substances are very similar. This creates an unnecessary amount of regulatory effort to ensure the different controls are complied with where programs trial several substances at any one time. This additional complexity, time and cost of seeking substance specific containment approvals has significantly hindered registrants' ability to conduct trials and puts New Zealand's system out of step with the rest of the world. It adds a further reason for companies not to do trial work in New Zealand.

4.10 Under the previous system, registrants could quickly respond to opportunities, such as if a particular sector indicated a strong interest in trialling a particular product currently used overseas. Registrants could also freely make small changes to formulations, which occurs commonly in research and development, without needing to apply for a new approval every time, waiting for what is typically 3 to 6 months from the date an application is submitted to when a decision is made. This is despite the applicable timeframe under the Act being 30 working days.

4.11 The result of making trial work more difficult is that it becomes more difficult to introduce new, typically safer, products to the New Zealand marketplace. We note that at least some data is required to be generated in NZ by the ACVM group when seeking registration, so this is not a step that registrants can bypass by using solely studies produced overseas.

4.12 New Zealand's small market coupled with a difficult regulatory environment for experimental products means that many companies are choosing to invest their research budget in other countries. Agcarm has obtained information from its members which has shown that many trials have been postponed or cancelled as a direct consequence of the EPA's changes to the containment approval system. This is also reflected in the work done by other companies that support research in NZ. One of the major analytical laboratories in NZ advised Agcarm that the amount of residue-testing work they conduct has dropped by over 40% since 2016.

4.13 Agcarm understands that this change in approach was due to concerns within the EPA that they were only supposed to approve applications which specified the particular substances up front. Agcarm has been trying to work with the EPA towards a solution for this problem for several years now with no success. We have proposed that the EPA create a group standard (See part 6A of the Act). for substances to be used solely in trials, which is the most efficient way to regulate experimental plant protection products (and would be similar in practice to how they are regulated in Australia for example).

4.14 Agcarm's view is that section 96B (2)(a) of the current HSNO Act, which describes Group Standards, makes it clear that a group standard can be issued for substances that are only to be used in containment, however the EPA has said that it disagrees. We request that the select committee amend the Act to either make it explicitly clear that group standards can (and should) be issued for such purposes, or create another section of the Act which would allow for containment approvals to be issued in a format that is similar to how they used to operate. Doing so would make NZ's product trial system far more consistent with that of overseas regulators. Given that this bill is about making better use of overseas information, we consider it appropriate that it also adopts systems used overseas that are superior to our current one.

4.15 The change in approach to containment approvals has not only significantly hindered the introduction of new active ingredients to NZ, it has also exacerbated the backlog of application work that the EPA is faced with, without making any material risk reduction impact. This is demonstrated by the EPA's own communications and updates.

4.16 The EPA's monthly Hazardous Substance update includes all decisions that were made during the previous month. I.e. the report sent out in March will list decisions made in February. Over the last three HS Updates the EPA has issued 21 containment approvals but just 5 "release" approvals in total. Release approvals are approvals which allow for a substance to be commercialised. These figures are a significant shift from what the EPA historically has processed.

4.17 We have not been able to find overall application figures for the last 3 years, however looking at EPA annual reports for the three years before that, the total number of containment approvals issued annually ranged between 12 to 15 while the total number of release approvals ranged from 86 to 98. The figures from the recent HS Updates demonstrate that the EPA is spending far more time processing containment approvals and less processing new applications – which are required for new products to actually enter the market.

4.18 This same trend was communicated to Agcarm members in a presentation from the EPA in November 2020, where the EPA reported a significant decrease in the number of release approvals, and a significant increase in the number of containment applications they have to process. This allocation of resources where the risks are the lowest (application of small amounts of future plant protection products in highly a controlled manner) is not the best use of resources and does not fulfil the intention of the Act.

4.19 Amending the HSNO Act to explicitly enable trial/containment approvals to either be granted as they previously were, or for registrants to follow a group standard when conducting a trial, will allow the EPA to focus their efforts on applications that result in new products entering the market, benefiting all stakeholders.

EPA processing timeframes

4.20 The EPA has become extremely slow at processing applications and these significant delays, as well as the unpredictability that they bring, make it difficult for registrants to justify to their global partners that NZ should be a market that they continue to try and introduce new active ingredients into. The introduction of new 'greener' products brings clear benefits to NZ as these are usually less hazardous than older products.

4.21 The EPA's slowness may have not been brought to the committee's attention before because when the EPA used to report application numbers in their annual reports, they usually said that 100% of applications were processed within statutory timeframes. The main explanation for this is that the EPA has, for several years, waived the applicable timeframes on most applications under section 59 of the Act. Occasionally this is because there is data lacking from an application which is necessary in order for the EPA to assess it. More recently however, waivers have been issued for generic reasons such as to provide enough time for the EPA to assess the application. Once a timeframe is waived, then the EPA can take as long as they wish to process an application, and still not technically exceed the statutory timeframe, as the timeframe no longer applies.

4.22 The second explanation for this is that the EPA currently treats applications as though they have not been received, if the EPA has not yet reviewed the application and the either of the applicable invoices have not yet been paid – there is an initial invoice of $1,000 followed by the remainder of the application fee. Agcarm members have no issues with waiting for payment before assessment starts, however the EPA will not usually raise the second invoice until an advisor has reviewed the application.

4.23 Up until late 2018, the EPA operated an approved customer system where regular applicants who paid their bills on time were treated as though they had paid the invoice for that application on the day that the application was submitted. At the time registrants were told that the introduction of an online credit card payment system was in the near future but this has not yet eventuated. Now that this system is no longer in place, there is no way for applicants to "start the clock" on the timeframe

This could be fixed by requiring the EPA to formally receive an application once the lodgement fee has been paid, as well as requiring the lodgement invoice to be issued soon after an application is lodged, which the EPA currently do. In addition, given global technology developments it would also be timely for the EPA to introduce software to allow direct online payment by credit card. It is surprising to Agcarm that this technology has yet to progress and remains unavailable.

4.24 Applicants are often faced with several months of no informative feedback from the EPA as to the progress of a newly submitted application, despite repeated requests for updates. This is unacceptable, particularly in light of the fact that many of these applications are supposed to be processed by the EPA in either 10 or 30 working days. Applicants are regularly waiting upwards of 4 months before receiving any feedback or the second invoice to commence processing. Often, as soon as they pay this invoice the EPA waives the applicable timeframe with a generic reason provided too. Recently some Agcarm members have reported experiencing delays of over 9 months before receiving any feedback.

4.25 We note that 10 working days is the same timeframe in which passport renewals are supposed to be processed. We encourage the members of the committee to think about how they and their constituents would respond if upon receiving an application for your passport renewal, DIA did not consider the 10-day timeframe had started for upwards of 4 months, and during this time the only feedback that they provided was that they hadn't yet assigned your renewal to an advisor.

4.26 Agcarm does not believe that this current protocol is operating as the Act intended. Aside for section 55 which exempts certain information from the OIA, there is no discussion of pre-application processing, so the timeframes that the Act specifies should apply from when the EPA actually receives an application (or payment so long as the invoice is raised in a timely manner).

4.27 This slow processing is a significant issue because again, it discourages companies from wanting to invest in bringing new and/or alternative products to New Zealand. The lack of transparency around the actual timeframes that the EPA is operating under is also an issue as it makes effective oversight difficult. If the select committee and others who have oversight of the EPA such as Ministers David Parker and the Hon Phil Twyford currently, only see that the EPA is meeting 100% or most of their statutory timeframes, then they are not being accurately informed about the EPA's performance and will not be able to make informed decisions about ways to help, such as considering an increase in resourcing.

4.28 In the past the EPA has genuinely met most (~80%) of the timeframes for applications they received. Through changes to EPA operational policy Agcarm thinks this can be achieved again. However, where there are options for legislative change to help with this, such as amending the sections that relate to containment approvals, so that the EPA only processes one application from a registrant every few years, rather than one every month or two, we encourage the select committee to adopt these changes.

4.29 We also encourage the committee to recommend amending section 59 of the Act so that time waivers be set only for specific set periods of time rather than be indefinite. E.g. allow for the EPA to waive a timeframe by 5, 10, 20 or 30 working days, even if they also have the ability to do this a set number of multiple times (e.g. up to 3 times per application) where necessary. This will encourage the EPA to continue with processing applications to which waivers have been applied, rather than treating them as lower priority.

4.30 Consideration should also be given to amending the statutory timeframe that applies for applications containing novel active ingredients. The current maximum statutory timeframe of 100 working days is nowhere near sufficient for the EPA to process a release application for a new product containing one or more new active ingredients. These applications require a significant amount of work for both applicants and the EPA and a longer timeframe for assessing them should be introduced.

4.31 Implementing this change may require the Act to be amended so that different types of applications are better differentiated and can be subject to different timeframes under section 59. Currently the Act does not differentiate between various applications that are publicly notified. This means that an application containing a new active ingredient, and one containing an existing active ingredient which the EPA have publicly notified, are subject to the same statutory timeframe, despite there being significantly different amounts of work required.

4.32 Agcarm considers that there should be a longer timeframe set under the Act for applications containing new active ingredients as these inevitably require more work. We would support an increase in this so long as it is appropriate in length.

Changing the sequence of events for notified application to allow for better public engagement

4.33 Section 59 of the Act currently lays out the timeframes as well as stages that a notified application should follow. The current process means that the EPA opens an application for consultation before they have had an opportunity to conduct their assessment on it. This means that submitters are often left with just the application form on which to base their feedback. This has been raised as an issue by some submitters historically, who want to meaningfully engage but struggle to as they won't see the documentation from the EPA's initial assessment until well after the submission period has closed and get frustrated at the applicant who can't reliably predict all the controls that the EPA will choose to apply.

4.34 Overseas regulator usually publish a report of their assessment of the technical data that has been submitted to them before opening the application for submissions. This enables stakeholders to better understand the risks and benefits associated with an application, as well as whether the regulator has accurately captured how a substance will be used and the benefits it provides. We understand that the EPA has on some recent occasions waived timeframes under section 59 so that this can occur in NZ, however we think this should be the standard procedure, and not something that can only be done by the EPA resorting to workarounds by waiving the existing timeframes required for public notification.

4.35 For an application containing a new active ingredient which is publicly notified, the EPA will usually produce a science memo which includes a human health and environmental risk assessment. They usually also produce an assessment of the benefits as the EPA is required to consider these under part 2 of the Act, although we note that in some previous instances the EPA's assessment of benefits is somewhat cursory.

4.36 Agcarm considers that it will be beneficial to both registrants and submitters if the process for notified applications is rearranged such that submitters have an opportunity to base their feedback not only on the application form, but also the EPA's advice. This should always include both a draft science memo and an initial assessment of the substance's benefits by the EPA. We recommend that the timeframe and sequence of events described by section 59 (1) are changed to enable this to occur. Increasing the timeframes that apply to such applications, as suggested in points 4.30 and 4.32 of our submission, can accommodate this.

5. 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.

For over 70 years, Agcarm has taken a lead role in managing issues of importance to the crop protection and animal medicines industries. This involves engaging with politicians, regulators and stakeholders to ensure that decision-makers take account of industry's views. It also ensures that industry aligns itself with best practice in the management of pests and disease.

Our members research the safest and best methods to do this. In the crop protection industry, our manufacturers support the use of Integrated Pest Management (using all means available to tackle pests and disease). They research all means of control, including biologicals, to ensure the best and most sustainable result for farmers and growers.

Membership to Agcarm is voluntary, with all applicants requiring Board endorsement before being accepted. Agcarm backs this by ensuring all members comply with a Code of Conduct.

This Code certifies that Agcarm members meet industry standards. Compliance with it is a condition of membership - with companies required to meet a number of obligations. This includes complying with relevant legislation, participating in environmental stewardship programmes, acting ethically in product promotion and in accordance with the best interests of industry.

Protecting the environment is integral to this, with support and participation of the rural recycling programme Agrecovery being compulsory for members. Companies must also ensure that their products meet an appropriate standard, all people involved with industry products are appropriately trained, and that they are supportive of ensuring environmental sustainability.

In promoting a healthy environment, Agcarm is involved in a number of other stewardship campaigns, within the crop protection and the animal medicines industries.

Bee health is high on the association's agenda with regular campaigning to protect the wellbeing of New Zealand's bee population, and ensuring that products are used responsibly. The 'Bee Responsible' awareness campaigns were produced in conjunction with the Rural Contractors and Agricultural Aviators associations to raise awareness of the importance of protecting bees and providing guidance for doing so.

Preventing resistance management in animals and plants is another priority for the association and its members. As part of this, Agcarm leads and supports programmes that prolong the effectiveness of crop protection and animal health products liable to encounter resistance problems, and limit losses should resistance appear.

This includes an integral role in the Wormwise Trust - providing expert advice to farmers on managing worms on farms (anthelmintic resistance) as well as antimicrobial resistance. Agcarm contributed to New Zealand's Antimicrobial Resistance Plan which was submitted to the World Health Organisation in May 2017.

The association's ultimate purpose is to ensure that New Zealand continues to lead the world in producing safe, healthy and sustainable food by using the best and safest technology. By dealing with an Agcarm member you too will be part of this worthy goal. So, next time you are considering a purchase of a pesticide or animal medicine, ask if the company is an Agcarm member and if they are you can be assured that you are dealing with knowledgeable staff and a quality product.

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

- Boehringer Ingleheim
- Ceva Animal Health
- Donaghys
- 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

- BioGro
- Zespri
- HortNZ
- NZKGI
- Kiwifruit Vine Health
- 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
- Tracta
- IPPC
- Redcap solutions
- De Groot
- Ranfurly Orchard Services
- FieldTek
- On Regulatory
- De Sangosse
- Educhem
- JP Munro
- AS Harrison
- AgRecruit
- Dechra