Australian Government

Australian Pesticides and Veterinary Medicines Authority

Response to the Productivity Commission Draft Research Report on Chemicals and Plastics Regulation

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1 Introduction

The APVMA welcomes the opportunity to comment on the Commission's draft report. We see this study as an opportunity to achieve improved efficiencies in the administration and delivery of chemicals regulation, without compromising the policy objectives of ensuring the protection of the health and safety of people, animals and crops, the environment and trade.

The report contains several draft recommendations of direct relevance to the APVMA including:

- Draft Recommendation 3.1 – the establishment of a specific chemicals standing committee.
- Draft Recommendation 4.5 – inclusion of the objective of maximizing net community benefit in agricultural and veterinary (agvet) assessment procedures.
- Draft Recommendation 4.6 – vertical integration of control-of-use to create a single national regime.
- Draft Recommendation 5.9 – automatic incorporation of MRLs set by the APVMA into the Food Standards Code.
- Draft Recommendation 6.3 – continue recognition of APVMA approved labels as appropriate for workplace purposes.

In this submission we have provided comment on each of these draft recommendations and on a number of the comments included in the draft report not resulting in a recommendation. We have also provided comment on Draft Recommendation 8.1 (establishment of an independent environmental standard setting body) although we understand that draft recommendation relates to industrial chemicals rather than agvet chemicals. Draft Recommendation 5.9 (separating the scheduling of poisons and drugs) is also of relevance to the APVMA's operations. However as the APVMA is a downstream recipient or user of scheduling decisions and the draft recommendation does not relate to the matters within APVMA's scope of responsibility we have not commented on it.

We note that with respect to agvet chemicals regulation the draft report contains several references to our two prior formal submissions to this study, submissions 59 and 65[1]. These are referred to as the 'primary submission' and the 'second submission' respectively in the following discussion.

2 General Comments

The APVMA is broadly supportive of the draft report. The regulatory framework for chemicals management in Australia has cross-jurisdictional divisions of power and responsibilities. This can be intricate and the draft report proposes a number of recommendations with the potential to improve the efficiency of the delivery of regulation.

[1] The APVMA's previous submissions are available from the Productivity Commission website at http://www.pc.gov.au/study/chemicalsandplastics/docs/submissions.

With consideration that the fundamental principle of this study is to assess the impact of unnecessary regulatory burdens on productivity we note that limited quantitative information appears to be available regarding the cost/productivity impacts associated with regulatory burdens. In order to fully separate the unnecessary costs arising from the existing stock of regulation from the underlying or necessary cost (i.e. quantifying the unnecessary burden), it would seem critical that quantitative data be available, particularly as perceptions between different stakeholders can be diverse. Given this, and the current lack of data, the APVMA reiterates its support for further research in the area of quantitative cost effects of regulation. Such cost estimates would better inform government on the actual, as distinct from the perceived, effects of regulation on productivity and competitiveness in the chemicals and plastics industry.

In this submission we have focussed our comment on the background and basis underpinning the recommendations and significant comments that are of relevance to the APVMA's operations. However in our consideration of the draft report we have also noted some minor errors of terminology or fact that do not appear to have impacted or effected the draft recommendations, the most significant of which include:

- the discussion in the draft report incorrectly assumes that the National Registration Scheme (NRS) for agvet chemicals only encompasses regulation up to the point of retail sale. The NRS also encompasses control-of-use, which is administered by the states and territories. This is discussed further in section 5;
- the discussion relating to the '*Quality and rigour of APVMA assessments*' (page 78 of the draft report) suggests that state governments undertake efficacy 'testing' for the APVMA. This terminology is not correct. Chemical sponsors (applicants) undertake efficacy testing (the conduct of efficacy trials) and submit the resultant data with their application for registration. It is the evaluation of that data that may be undertaken by reviewers in state government departments.
- Appendix B '*Overview of current regulatory arrangements*' for agricultural chemicals (page 263 of the draft report) suggests that the Australian Safety and Compensation Council (ASCC) examines occupational health and safety (OH&S) issues. This is incorrect. As identified elsewhere in the draft report the APVMA obtains OH&S advice from the Australian Government Department of Health and Ageing's (DoHA) Office of Chemical Safety (OCS).

Whilst the APVMA is generally supportive of the draft recommendations of relevance to its operations, the specific intent of some of the draft recommendations is not always clear from the text of the draft report. We believe that a number of the draft recommendations would be strengthened by the inclusion of further detail, particularly with respect to their scope, removing any subjectivity or openness to interpretation. Furthermore we anticipate that the implementation of some recommendations, should they be accepted by Government, would be aided if detail as to the Commission's views on their functional application were provided in the final report. The following discussion relating to the draft recommendations and comments of relevance to the APVMA highlights those areas in which we believe additional clarity in this respect is warranted.

3 Draft Recommendation 3.1

Subsequent to the COAG ministerial taskforce on chemicals and plastics regulation having completed its reference, the Commonwealth, states and territories should establish, under the Australian Health Ministers' Conference, a Standing Committee on Chemicals comprising representatives of all ministerial councils that have responsibility for chemicals regulation. It would:

- provide an ongoing forum for assessing:
  - the consistency of chemical-specific policy settings across the various areasof concern, including public health, workplace and on-farm safety, transport safety, environment protection and national security
  - the effectiveness and efficiency of the overall chemical-specific regulatory system
- address emerging issues such as nanotechnology
- oversee the consistent application of chemicals hazard and risk-assessment methodologies
- make recommendations for specific actions by individual ministerial councils.

Comments:

The APVMA strongly supports the establishment of a formal mechanism to improve cross-portfolio policy coordination and the efficiency of chemicals regulation. As discussed in the APVMA's primary submission (section 9.1) we believe that the key advantages of a cross-portfolio committee lie in assuring that:

- product responsibility is adequately differentiated between regulators and that product groups that have multiple uses do not have duplicative regulatory requirements;
- assessment methodologies are consistently applied for risk areas that are managed for different uses;
- a whole-of-government consistent approach is applied to chemicals management, particularly in the area of emerging technologies; and
- through review, the legislation underpinning each regulator's responsibilities is consistent with risks posed and that legislation and policy applied in one area is considered for application to another area of regulation.

The APVMA notes the Commission's comment that "*The committee would be a forum for the exchange of ideas and information and would also provide recommendations to the respective ministerial councils on how chemical policy initiatives that have cross portfolio implications might be best progressed*". We support this comment and believe such a forum would facilitate the delivery of the above key advantages.

The draft report recommends that the Standing Committee on Chemicals (SCOC) report to a Ministerial Council, proposing its establishment under the Australian Health Ministers' Conference (AHMC) with a charter ensuring it operates as a cross-portfolio coordinating committee. We agree that such a standing committee should have appropriate governance and accountability structures (through reporting to Ministers). However as that committee is intended as a cross-portfolio forum for policy coordination

that would provide recommendations to the respective Ministerial Councils involved in the various facets of chemicals regulation[2], we consider the proposal for SCOC to report to the AHMC as unnecessary and potentially limiting. Such reporting arrangements may also over time influence or confound the intended cross-portfolio charter. The APVMA believes that an appropriate level of governance and accountability for SCOC could be provided through its report to each of the respective stakeholder Ministerial Councils, with whole-of-government accountability and oversight continuing to be provided through the Council of Australian Governments (COAG) process.

Development of models for SCOC

In developing its original proposal for the establishment of a formal cross-portfolio forum, the APVMA envisaged that a SCOC-type structure would be a subcommittee of each of the respective Ministerial Councils (or their Standing Committees) comprising senior operational and policy officers. We believed that chemicals policy should continue to be formulated within the respective portfolios (with cross-portfolio consultation between the respective standing committees or policy groups as is currently the case) but formally considered from a cross-portfolio or whole-of-government perspective through the SCOC before finalisation and implementation. This would facilitate the identification and rectification of any impacts, flow-on effects or inherent duplication. We believed that in-principle policy agreement could be brokered where necessary at the SCOC between affected portfolios and that the SCOC could subsequently make recommendations to the relevant Ministerial Councils (through their Standing Committees) about necessary actions. The Ministerial Councils would then (through their committee structures) consider the SCOC recommendations, liaise with other impacted Ministerial Councils if necessary, undertake action where required and report back to the SCOC.

In terms of overarching governance the APVMA envisaged that the impetus or authority of the SCOC structure would be provided through an oversight report to COAG. As such, should a circumstance arise where in-principle agreement could not be reached between affected portfolios through the SCOC structure, or where issues identified through SCOC remained unresolved, the future direction for the resolution of those matters could be informed through the COAG process. In this respect we believed that a SCOC-type structure would complement the existing intra-portfolio policy development mechanisms (which include state and territory input through avenues such as the Product Safety and Integrity Committee) and that the SCOC would primarily provide inter-portfolio policy coordination. We have attempted to represent this type of model (model 1) diagrammatically in Attachment 1.

The APVMA proposed the inclusion of operational officers in conjunction with policy officers for a SCOC-type structure because we believe that ‘on the ground’ knowledge and experience would help inform discussions in relation to regulatory matters such as clarity over the scope of products regulated by particular regulators and the standardisation of assessment methodologies.

[2] Namely the Australian Transport Council (ATC), the Australian Health Ministers Conference (AHMC), the Workplace Relations Ministerial Council (WRMC),the Environment Protection and Heritage Council (EPHC), the Primary Industries Ministerial Council (PIMC) and COAG for security concern chemicals

An alternative model for the operation of a SCOC-type structure would be for each of the respective Ministerial Councils to refer responsibility for policy development directly to the SCOC. Under such a model policy advice would continue to be provided by the same agencies or committees as is currently the case, but the policy advice would be provided direct to the SCOC rather than to a Ministerial Council Standing Committee. The respective Ministerial Councils would retain a primary policy oversight role within their respective portfolio and deal with SCOC outcomes and recommendations as in the previous model. The interests of the respective Ministerial Councils and their stakeholders would be protected at the SCOC by its membership comprising representation from the respective Standing Committees, as well as through the provision of policy advice from the subordinate policy agency or committee. Whilst policy advice for agvet chemicals is provided through the Product Safety and Integrity Committee (PSIC), which includes state and territory representation, we understand that similar committees do not exist across all portfolios. Under this alternate model stakeholder confidence may be enhanced by the inclusion of similar policy advice committees from all portfolios. We have attempted to represent this alternate model (model 2) diagrammatically in Attachment 2.

As was the case for model 1, under model 2 governance and accountability for SCOC could be provided through its report to each of the respective stakeholder Ministerial Councils with the overall impetus or authority for the SCOC provided through an oversight report to COAG. The key difference of model 2 is the effective substitution of the SCOC for the existing Standing Committee arrangements, with the SCOC taking more of an inter-portfolio policy development role. Under model 1, policy development remains within the respective portfolios and the SCOC undertakes an inter-portfolio policy coordination function.

Model 1 complements existing policy development frameworks and would satisfy the aims identified by the Commission in the draft report (to provide a forum for the exchange of ideas; to make recommendations to the respective ministerial councils on how chemical policy initiatives that have cross portfolio implications might be best progressed). Such a framework (or something of that nature) offers advantage in terms of ease and speed of establishment as well as effectiveness. Although it may be argued that model 2 has the potential to create efficiencies and reduce duplication, policy development (rather than coordination and refinement) in such an environment could have the potential to become unwieldy, impacting the timeliness of outcomes.

Although the draft report identifies the aims of a SCOC structure and suggests the committee's ongoing role, the Commission's intention with respect to the type of operational framework (or membership) for such a committee is not clearly documented. As the establishment of such a committee may be beneficial to the subsequent implementation of a number of the recommendations arising from this study, further guidance in the Commission's final report may aid in the establishment of a SCOC structure consistent with the Commission's expectations.

Secretariat support for SCOC

With respect to the provision of secretariat support for SCOC the APVMA believes that this function could be rotated annually between the stakeholder portfolios, perhaps in

conjunction with the SCOC chair position. This would reinforce the true cross-portfolio nature of SCOC and could potentially encourage greater engagement of stakeholder portfolios and agencies. It would also share the resource or administrative burdens associated with the committee's operation.

4 Draft Recommendation 4.5

An objective of the National Registration Scheme for agricultural and veterinary chemicals should be to maximise net community benefit, and its assessment requirements and outcomes should be supported by analysis of the associated costs and benefits.

Comments:

In the draft report the Commission has highlighted that regulatory obligations impose costs and generate benefits to the public. The APVMA agrees that regulatory intervention should be targeted so that regulation provides a net community benefit.

The draft report states that the *Agricultural and Veterinary Chemicals Code Act 1994* (the Agvet Code) does not recognise the generation of net community benefit as a goal. Whilst it is perhaps not explicitly stated, the APVMA wishes to highlight that the preamble to both the *Agricultural and Veterinary Chemicals Act 1994* and the Agvet Code does recognise the benefits to the Australian community and economy of having in place a system to regulate agvet chemical products. In particular it is recognised, amongst other things, that:

- the protection of the health and safety of human beings, animals and the environment is essential to the well-being of society; and
- trade, the economic viability and competitiveness of Australian primary industry and of a domestic chemical industry are essential for the Australian economy, necessitating a regulatory system that is cost effective, efficient, predictable, adaptive and responsive.

These matters underpin the administration of the regulatory powers provided by the Act. There are also reflected in the APVMA's mission "*To protect the health and safety of people, animals and crops, the environment, and trade, and support Australian primary industries, through evidence-based, effective and efficient regulation of pesticides and veterinary medicines*".

The APVMA is highly supportive of the delivery of effective and efficient regulation and in our two prior submissions to this study we have highlighted a number of the key reforms within the scope of the APVMA's operations that we are progressing. These reforms will improve the efficiency of the regulatory process and reduce regulatory burdens. The fundamental aim for regulation is to be effective in addressing identified problems and efficient in terms of maximising the benefits to the community, taking account of the costs (Best Practice Regulation Handbook[3]). This ethos underpins the

[3] The Office of Best Practice Regulations' Best Practice Regulation Handbook is available at http://www.obpr.gov.au/bestpractice.html.

regulatory impact assessment (cost/benefit analysis) and regulatory impact statement process associated with the making of new regulation. It also underpins the type of reform activities being undertaken by the APVMA.

The APVMA notes that draft recommendation 4.5 suggests that APVMA assessment requirements and outcomes should be supported by analysis of the associated costs and benefits. Whilst regulatory impact assessments apply to the making of new regulation or quasi-regulation (which includes regulatory requirements such as significant new information requirements) they do not currently apply to the making of regulatory decisions in accordance with those regulations. Making new regulations and making regulatory decisions are distinct activities associated with regulating.

We believe that cost-benefit analysis should not apply to regulatory decisions, such as whether to register a chemical product or not, due to the potential complications that would pose. For example it could potentially be difficult to reconcile the protective role of regulation with the outcome of a cost-benefit analysis where a new chemical product applied to food was found to be highly likely to cause cancer or some other critical adverse effect in 10 per cent of the population, but its availability and use was likely to produce significant benefit for the remaining 90 per cent of the population (for example by controlling a pest or disease of agricultural significance) – such an analysis for this example would require a value judgement to be made in respect to whether the benefits outweighed the costs. Further, the additional data and assessment requirements to support the cost-benefit analysis of each registration decision could impose a significant additional regulatory burden for which the associated benefit would need to be fully considered.

It is however relevant to note that section 93 of the Agvet Code does currently include a requirement for the APVMA to satisfy a public interest test when considering whether to determine a chemical product to be a restricted chemical product. Products declared to be restricted chemical products are effectively subject to a greater degree of regulatory interest in terms of post-registration control. As such, the restricted chemical product public interest test is aligned with the Office of Best Practice Regulation framework for the consideration of new or additional regulation.

The APVMA understands that a key area of interest for the Commission in terms of promoting the recognition of costs and benefits in chemical regulatory process is a more explicit recognition of the concept of risk management in a regulator's empowering legislation – risk management necessitates a balancing of costs and benefits so that regulatory outcomes (decisions and actions) are commensurate with the identified risks. For example the New Zealand *Hazardous Substances and New Organisms Act 1996* (HSNO Act) stipulates that its purpose is to "…protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms" (section 4) and identifies as a matter relevant to the purpose of the Act "the economic and related benefits and costs of using a particular hazardous substance or new organism" (subsection 6(e)). Whilst the application of this principle in the administration of the HSNO Act appears to be balanced by a legislative requirement to "…take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects" (section 7, precautionary approach), it is acknowledged that the Act does contain

explicit reference to costs and benefits and consequently the application of risk management.

Nevertheless the consideration of practical risk management options is a fundamental component of the APVMA's process of becoming satisfied to approve an active constituent or register an agvet chemical product – the regulatory process is based on the management of risks. It is only when all potential risk management options have been explored and determined to be unable to manage or mitigate the relevant risks that the APVMA will refuse an application. The current assessment process provides considerable opportunity for an applicant to vary their application to overcome identified risk management issues or to provide new information.

With respect to the reconsideration of existing chemicals (chemical review) the Agvet Code currently requires the application of risk management where the APVMA determines that it may not remain satisfied to continue the approval of an active constituent or the registration of an agvet chemical product. Section 34 of the Agvet Code requires the APVMA to consider whether the particulars or conditions of approval or registration may be varied in order for the APVMA to remain satisfied – this includes the consideration of alternate risk management options. A similar requirement to consider alternate risk management options in respect of decisions to register new products (section 14 of the Agvet Code) would underpin existing regulatory process and may assist to alleviate the Commission's concern.

5 Draft Recommendation 4.6

The National Registration Scheme for agricultural and veterinary chemicals should be extended to cover regulation of agricultural and veterinary chemical use after the point of retail sale, provided:

- the new national regime contains appropriate exemption provisions and is administered at state and territory level, to allow adequate flexibility to address local issues
- there is a commensurate reduction in regulatory burden at state and territory level.

Comments:

The National Registration Scheme (NRS) for agvet chemicals is a partnership between the Australian, state and territory governments established in 1995 by intergovernmental agreement of the respective agriculture Ministers at the time. As highlighted in the APVMA's primary submission to this study the NRS is established in this way because of constitutional limitations on the Commonwealth's ability to legislate over agvet chemicals. The regulatory framework of the NRS is a complementary one with a shared division of responsibilities between the Commonwealth and the states and territories.

The discussion in section 4.3 of the draft report suggests that the NRS only includes regulation up to the point of retail sale. This is not correct. Whilst the APVMA regulates the supply of agvet chemicals in the Australian marketplace up to and including the point

of retail sale, each state and territory then regulates the use of agvet chemicals in its respective jurisdiction (control-of-use). This partnership is the NRS.

Although the recommendation proposes extending the NRS to include regulation after the point of retail sale (which as described above is already included in the NRS) from the Commission's discussion of the vertical integration of control-of-use regimes to create a uniform national regime, we understand that the intent of the recommendation is to incorporate the administration of control-of-use activities into the APVMA's activities. The Allen Consulting Group report, *A National Risk Management System for Agvet Chemicals-Positioning for the Future*[4], delivered in 2002 (discussed in section 4.2 of the APVMA's primary submission) similarly proposed vertical integration within the agvet regulatory framework. Those recommendations were considered from a policy perspective and at that time PSIC determined that improved consistency in regulatory outcomes could be most efficiently achieved through the adoption of national operating principles (discussed in section 4.3 of the APVMA's primary submission). However it is acknowledged that there remains considerable variability in regulatory approaches between the respective jurisdictions as highlighted in Table 4.4 of the draft report.

The Commission will be aware that the current state and territory responsibility with respect to the regulation of agvet chemicals after the point of retail sale is not just limited to control-of-use enforcement functions. As highlighted in the APVMA's primary submission to this study (section 5.2), the state and territory role includes components vital to chemical management such as training, licensing, residue monitoring as well as the administration of codes of practice, policies, guidelines and other user-awareness raising activities. The APVMA notes the Commission's comments in relation to the continued role of states and territories in 'on the ground' administration and we presume these arrangements would remain. However it would be helpful if the Commission were able to clarify whether it is intended that the 'national code' referred to would encompass these related activities or only the control-of-use enforcement functions.

As the intent of the recommended vertical integration is to improve national consistency in terms of regulatory control after the point of retail sale, the APVMA believes further clarity is required with respect to the Commission's comments about the maintenance of flexibility to meet local circumstances. It is unclear where such flexibility would be required. Geographic and climatic (agronomic) variance between the regions in which agvet chemical products may be applied (e.g. soil types, rainfall, temperature etc) is accounted for through label instructions. Variations such as off-label use which may be required to account for pests or diseases (or crops and animals) for which there is no registered product (or other situations for which a varied instruction is required such as unique local circumstances) are be best managed through the APVMA permits scheme, which facilitates both off-label and emergency uses.

Noting the constitutional limitations on the Commonwealth's ability to legislate over agvet chemicals, in order to broaden the Australian Government's primary leadership role in the NRS (through the APVMA) it would be necessary for the states and territories to

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[4] Allen Consulting Group, 'A National Risk Management System for Agvet Chemicals—Positioning for the Future', *A strategic review for the National Registration Authority for Agricultural and Veterinary Chemicals*, 2002. (available at www.allenconsult.com.au)

confer additional powers to the Commonwealth. This would be a matter for negotiation between the Commonwealth, states and territories. Nevertheless noting the significant benefits that have been obtained through the creation of the NRS in terms of streamlining registration and review processes and with consideration that the scheme has been operating for over a decade it may be appropriate for the structure of the scheme to be revisited to ensure it continues to meet contemporary needs.

The APVMA currently operates on cost-recovery principles – its operating costs are recovered from the chemical industry through fees and a levy. In contrast, the control-of-use functions (and related activities) are budget funded by the states and territories. In order to progress this recommendation it will be important for consideration to be given to the funding options for a vertically integrated nationally scheme. The current Australian Government Cost Recovery Guidelines (July 2005)[5] suggest that the costs of such activities where administered by an Australian Government department or agency (such as the APVMA) could be subject to cost-recovery principles. With reference to the comments in the draft report that a vertically integrated scheme would be intended to decrease costs to suppliers and users of agvet chemicals, it would be beneficial if the Commission were to provide further clarity as to its position on the matter of funding.

6 Other Comments Relating To Chapter 4

6.1 Separation of risk-assessment and risk-management functions

Chapter 3 of the draft report states that standard-setting involves designing the risk management rules by which chemicals and plastics are regulated. The diversity of the type of standards is also discussed, ranging from high-level policy standards to chemical-specific standards. However the discussion does not clearly delineate all the types of standards and the level at which they are set. As a result the specific intent of references to 'standards' at various places throughout the draft report is unclear.

Chapter 4 of the draft report states that APVMA functions include both agvet chemical risk assessment and subsequent standard setting to manage the risks of using agvet chemical products. The draft report would be strengthened by including recognition that a significant number of the standards associated with the risk management of agvet chemicals are set by the other agencies. For example the Office of Chemical Safety (OCS) within the Department of Health and Ageing determines the Acceptable Daily Intake (ADI), the Acute Reference Dose (ARfD) and the No Observed Effect Level (NOEL). These are exposure standards that underpin other assessments such as dietary and occupational exposure. The OCS also classifies chemical hazard in accordance with a national framework for hazard classification (a standard) and where necessary recommends first aid and safety instructions (which includes personal protective equipment) to ensure worker exposure does not exceed occupational health and safety standards. Similarly the Department of the Environment, Water, Heritage and the Arts (DEWHA) considers the potential hazards of a chemical as well as the likely exposures

[5] Available from the Australian Government Department of Finance and Deregulation website at http://www.finance.gov.au/finframework/docs/Cost_Recovery_Guidelines.pdf.

and recommends risk management strategies to ensure any environmental exposures are acceptable and do not exceed any relevant tolerances.

The APVMA through its residues assessment determines a Maximum Residue Limit (MRL). The APVMA may also determine standards for active constituents and products, as well as criteria (standards) for the demonstration of efficacy. Importantly, the APVMA determines and approves the ultimate standard for agvet chemical product use – the product label. The label is a standard for product use because its observance/enforcement ensures compliance with public health, occupational health and safety, environmental protection, trade and efficacy objectives and compliance with any national standards pursuant to those objectives.

The APVMA notes the Commission's comments relating to the separation of risk assessment and risk management functions and that in the case of the APVMA most of the scientific assessment is already outsourced to other agencies. It is true that the only primary assessment activities undertaken by the APVMA are the residue assessment (including trade) and the chemistry assessment. As such the APVMA is primarily a risk management agency with an effective separation of assessment and standard setting functions – arrangements that align to the four-tier best practice governance framework proposed by the Commission.

6.2 Reconsideration of existing chemicals

The reconsideration (review) of existing chemical products is invariably complex, contentious and resource intensive. Whilst the APVMA acknowledges the concern with respect to the timeliness of chemical reviews and is working to develop strategies for further improvements in this regard, we wish to highlight that where areas of significant concern are identified with a particular chemical or class of chemical products the APVMA can and does take rapid action to manage those risks. As acknowledged in the draft report, the APVMA is currently conducting a review of its current approach to chemical review. With respect to timeliness that work will include some international benchmarking to quantify Australia's performance in this regard with that achieved by comparable agencies internationally.

As the Commission will be aware the APVMA's chemical review activities are currently funded through the APVMA's cost-recovery arrangements. We note the Commission's comments with respect to draft recommendation 4.4, that the costs of accelerating the National Industrial Chemical Notification and Assessment Scheme (NICNAS) program for the assessment of existing chemicals, which is in the broader public interest, should be met from budget funding. The cost-recovery arrangements for the APVMA are currently under review[6]. With consideration that the APVMA's reassessment of existing chemicals is also in the broader public interest, the cost-recovery review may provide an opportunity for the consideration of funding options for the APVMA chemical review program. The Commission's views in this regard may help inform that review process.

[6] Further information on the review of the APVMA's cost recovery framework is available from the APVMA website at http://www.apvma.gov.au/about_us/costrecovery.shtml.

6.3 Minor Use

The APVMA is actively involved in conjunction with the Australian Government Department of Agriculture, Fisheries and Forestry (DAFF) and its international counterparts to progress minor use initiatives and develop long-term strategies for addressing minor use (discussed in section 8.2 of our primary submission). The APVMA agrees that cost effective assessment processes for minor-use applications are integral to support impacted primary industries. However, perhaps more important is the management and funding of the costs associated with generating the technical data necessary to support minor use applications, as well as the availability of technical and regulatory expertise to compile those applications.

The commodity producer groups most successfully dealing with the minor use issue are typically those with statutory levies in place and the capacity to coordinate data generation and the compilation of submissions (for example the commodity groups with statutory levies through Horticulture Australia Limited). However a significant segment of the producer industries facing minor use difficulties have no or limited capacity for such coordination or funding. The APVMA can only sympathise with these groups where a lack of relevant data constrains its ability to consider and approve minor use permits. As identified in the draft report, a potential consequence in such circumstances is the illegal (unassessed) use of pesticides and the potential for adverse environmental, health (both public and worker safety) and trade consequences. Economic analyses conducted overseas of the net national benefits from the investment of public funds into facilitating the coordination and development of data for minor use applications have demonstrated favourable returns in terms of net public benefit per dollar invested[7], suggesting a potential role for government where such gaps exist.

With regard to the impact of regulatory burdens, in its consideration of minor use applications the APVMA ensures that data requirements are set a level commensurate with the potential risk. The APVMA can often be satisfied to issue minor use permits on the basis of little or no data, using extrapolated information from other similar crops. However it would be incorrect to assume that the risks associated with minor use are always low. Many minor uses are in horticultural crops that may be high consumption commodities with the potential to comprise a significant part of the Australian diet. Irrespective of whether a use is minor or major, the Agvet Code requires the APVMA to be satisfied that the proposed use will not cause undue harm to public health, workers, trade and the environment – that the risks of use are acceptable. In this respect the current regulatory approach is aligned to the Commission's support of reduced assessment requirements where it is apparent that the minor use results in a lower level of risk.

6.4 Utilisation of International Linkages

The APVMA has considered the Commission's comments relating to the use of international linkages and wishes to clarify the differences between the acceptance of information (data) generated overseas and the acceptance of completed international

[7] See Miller, S.R. (2007) National Economic Impact of the IR-4 Project. Centre For Economic Analysis, Michigan State University available at http://www.ir4.rutgers.edu/Other/IR4EconomicImpact.pdf.

assessments. Whilst the two are related, the draft report intermingles the discussion of each and does not clearly differentiate the different aspects pursuant to them.

International data

With regard to the acceptance of international data the draft report correctly identifies that the APVMA does take into account information generated overseas where it is relevant to an application. However the draft report states that the criteria on accepting international data have not been articulated. This is incorrect. The various data requirements chapters in Volume 3 of the APVMA's Manual of Requirements and Guidelines (MORAG)[8] set out the standards to which technical studies (data) must conform whether conducted in Australia or overseas, many of which are international standards. For example Part 3 (toxicology) of Agricultural MORAG states that "All toxicity studies must be conducted in accordance with the OECD Guidelines for the testing of chemicals or other recognised test guidelines, e.g. US Environment Protection Agency, Japanese Ministry of Fisheries and Food, and with an acceptable code of Good Laboratory Practice (GLP)". With respect to the format of the information MORAG states that "Data packages in the OECD format (as used in the European Union) or the United States are acceptable if they contain the data required by the relevant application category or toxicology module, and are appropriately indexed". Whilst the APVMA acknowledges that in some Chapters the guidance may not be as explicit, the same general principle applies – if data has been collected in accordance with an internationally accepted standard and it is relevant to the application at hand it will be acceptable to the APVMA.

As identified in the draft report differences in the use patterns proposed in Australia to those proposed overseas (for example different pests/diseases, crops/animals, rates) and differences in environmental and agronomic conditions between Australia and other countries can impact on the relevance of data generated overseas to registration proposals in Australia – the use pattern specific information. However this is also addressed in the data requirements chapters of MORAG. For example Part 5A (Residues) of Agricultural MORAG states that "Relevant data from residue trials carried out overseas may be submitted in support of an application. However, in most cases applicants will be expected to conduct, as a minimum, confirmatory tests under typical conditions of use in Australia to indicate the levels of residues under local conditions, and to validate any extrapolation from the overseas data…Australian residue data are required for agricultural chemicals whose use-patterns or conditions of use are different from those overseas". Similarly Part 8 (Efficacy) states that "In most cases, applicants will need to submit the results of properly designed and conducted laboratory and field studies that prove the efficacy and crop tolerance of the product…Data produced under Australian conditions are required in most cases, but relevant data from overseas may also be provided". Similar statements exist in Veterinary MORAG.

The issue of relevance of information submitted in connection with applications is straightforward irrespective of its country of origin. The information must support the claims being made for the use patterns proposed in Australia. If information generated

[8] The Manual of Requirements and Guidelines is available from the APVMA website at http://www.apvma.gov.au/industry/MORAG.shtml.

overseas is relevant to the Australian claims, it is acceptable. Typically the greatest opportunities for international portability of information lies in the areas of human and environmental toxicology. This is because much of this information is not use pattern specific and hence it remains relevant to a wide array of varied regulatory proposals (different use patterns) between countries.

International assessments

As discussed in the APVMA's primary submission to this study (section 6), the internationally accepted practice is for international acceptance of hazard assessment reports. The setting of standards and the application of risk management (a result of a risk assessment) are country specific due to societal differences in the acceptance of risk. As highlighted above there are also often differences between countries in terms of the specific use pattern that is proposed for the chemical, which logically drives the nature of the risk assessment. Different use patterns pose different exposure risks and necessitate use pattern specific risk assessments.

The APVMA is currently involved in a number of international work-share projects through the OECD. Through these work-share arrangements an individual country takes the lead on a specific aspect of the hazard assessment which, following peer review by the work-share partners, is accepted by all participants – that is the evaluations conducted by other regulatory authorities are accepted and used to make regulatory decisions. The draft report states that with the exception of OECD work-shares the APVMA has not entered into any formal arrangements to consistently accept aspects of other countries assessments. However as stated in the APVMA's primary submission to this study, work-shares are expected to lead to Australian Government acceptance (and indeed the acceptance of other international governments) of OECD consistent hazard assessment reports without the need for the Australian Government to be involved in the work-share itself – the uniform and consistent international acceptance of hazard assessment monographs is an intended outcome of the OECD work-share activities. The work-share peer review process currently being undertaken is building the international regulatory confidence to facilitate this. However the international acceptance of assessment monographs (reports) is different to the mutual recognition of registration/approval decisions. No OECD country applies the principle of mutual recognition of registration/approval decisions.

It is important to note that the acceptance of an international monograph does not negate the need for the relevant data (i.e. the data on which the assessment is based) to be submitted in the recipient country (e.g. Australia). In order to provide appropriate intellectual property protection it is internationally agreed practice that full copies of the relevant data are submitted with the international monograph in the country accepting the assessment. The APVMA believes that this may not be well understood by some sectors of the chemical industry arguing for Australian regulatory authorities to place greater reliance on overseas assessment reports. The use of such reports is only possible where the applicant owns or has access to the relevant intellectual property.

6.5 Consolidation of chemical assessment regimes

The APVMA agrees with the Commission's conclusion that there is not a sound case for amalgamating NICNAS and the APVMA. In addition to the reasoning provided in the draft report we believe that national regulators such as NICNAS and the APVMA are specialists in risk management within their respective industries. The APVMA's evaluation staff have particular expertise in the management of risks associated with chemical use in the primary sector – this expertise differs from that necessary to apply risk management to the use of chemicals in other sectors. Such specialisation ensures that the user industries are supported by relevant and effective regulation (this was discussed in section 9.2 of the APVMA's primary submission). We believe any potential interfacing issues between the key national regulators will be managed through the coordinating committee arrangements (the SCOC) recommended by the Commission (see section 9.1 of the APVMA's primary submission).

In terms of potential areas of improvement in national hazard and risk assessment we agree that opportunities for improved efficiencies and economies of scale may lie in the consolidation of specialist advice providers so that national regulators such as NICNAS and APVMA get their advice from the same agencies. As noted by the Commission some components of national exposure and risk assessment are currently quite dispersed. Consolidation, where appropriate, may bring a number of advantages such as improved national consistency and reduced administrative costs (further detail is included in section 9.2 of the APVMA's primary submission).

7 Draft Recommendation 5.9

Maximum residue limits set by the APVMA, which take account of dietary impacts using methods agreed with Food Standards Australia New Zealand (FSANZ) and the Australian Government Department of Health and Ageing, should be automatically incorporated into the Australia New Zealand Food Standards Code. Any decision to the contrary by FSANZ and the Australia and New Zealand Food Regulation Ministerial Council should be based on a cost–benefit analysis and be reported publicly.

Comments:

For a number of years the APVMA has actively participated in discussions with Food Standards Australia New Zealand (FSANZ) and the Food Regulation Standing Committee to streamline the MRL setting process. The APVMA agrees with the Commission's comments that recent reforms will only partially address the issue of timeliness for the promulgation of MRLs into the Food Standards Code, these MRLs having been determined as part of the APVMA risk assessment process.

The APVMA strongly supports draft recommendation 5.9 which will streamline and improve the efficiency of the MRL system with no change to the high level of assessment and safety provided as an outcome of the existing regulatory process.

With regard to the safety and confidence provided by the existing regulatory framework for MRLs, the Commission's recognition that the arrangements have been "…largely effective in keeping chemical residues in food to safe levels" is noted. However we wish to correct the Commission's assertion in footnote 23 of the draft report (page 137) that the Australian Consumers Association (ACA) survey of strawberries provides contrary evidence.

Subsequent to the drafting of the report, the APVMA has reviewed the ACA data obtained through FSANZ. From that review, it is apparent that only one residue may have been above the MRL, not three as reported. The APVMA has written to ACA requesting details of the testing methodology as well as numerous other survey parameters to establish the validity of the results – this information is yet to be provided. Nevertheless the APVMA assessment has determined that the one MRL violation (in the order of that suggested by the ACA survey), does not equate to a compromise in public safety. In light of the new information received, and the data reviewed by both APVMA and FSANZ, it would be incorrect to cite the ACA survey as providing contrary evidence at this point.

8 Draft Recommendation 6.3

Any new system for workplace hazardous chemicals labelling should recognise labels approved by APVMA as being sufficient for workplace requirements.

Comments:

The labelling system for agvet chemical products is a risk-based system. The workplace labelling system is a hazard-based system. Protection for persons who use agvet chemical products is delivered by specific use instructions on each label that are determined by a competent authority after a thorough risk assessment. In a hazard based labelling system the user makes the risk assessment based on the hazards identified on the label (this was discussed in detail in the APVMA's second submission to the study).

Where use is undefined and hence the potential exposure pathways are unknown or variable, hazard-based labelling systems offer the most appropriate regulatory solution by flagging potential hazards to workers and the environment. These systems aim to manage the risks of exposure through raising the user's awareness of the hazards and permitting the user to assess the risks and take the action they think appropriate to mitigate those risks. However where use is defined, risk-based labelling systems offer a sophisticated system of risk management and mitigation. Risks are managed by providing specific instructions that have been determined through expert scientific assessment.

In contrast to industrial chemicals, agvet chemical products are only registered for use in defined situations (authorised use patterns) by specified means (methods of application etc). Further, agvet chemicals are intentionally applied to the environment and food – consequently the outcomes from agvet chemical labelling are distinct from other sectors. Whilst the workplace labelling framework is limited to worker safety, the agvet labelling framework addresses not only worker safety but also public health (which includes residues in food), environmental protection, efficacy and trade.

The worker safety assessment in the agvet scheme is fully compliant with the occupational health and safety hazardous substances standards. The hazard classification methodology is the same as in the industrial chemicals system and the risk assessment methodology is highly sophisticated, considering matters such as frequency of use and the potential for chronic and acute exposure from the specified use patterns and application methods – it is unlikely that such detailed consideration and exposure modelling could be readily conducted by a user in the workplace.

The detailed worker safety assessment conducted through the agvet framework is necessary to satisfy the APVMA's legislative obligation to be satisfied that the use of the product in accordance with the instructions for use the APVMA approves would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues and would not be likely to have an effect that is harmful to human beings (as set out in section 14(3)(e) of the Agvet Code). In addition the APVMA is required to ensure that labels contain 'adequate instructions', which amongst other things, must include instruction for the re-entry period after the use of the product, the safe handling of the product, storage, disposal and first aid in the event of an accident caused by the handling of the product (see section 14(3)(g) of the Agvet Code) – such instructions ensure worker safety.

Where product use is defined and instructions for use are specified on the label the inclusion of additional information that would be commensurate with a hazard-based label would be redundant and confusing. In order to legally use an agvet chemical product a worker must follow the label instructions. As such were a worker to conduct an independent risk assessment replicating/repeating the risk assessment that resulted in the risk-based label instruction, the only outcome for legal chemical use would be to derive the same instruction.

The APVMA appreciates that occupational health and safety regulators may have some concern with draft recommendation 6.3. State and territory OH&S laws require that the chemical user (or employer) consider chemical use on the basis of overt hazard – they assume the need to make a risk assessment, as is necessary to ensure the safe use of industrial chemicals. However the use of agvet chemicals in a farm workplace is distinct in that agvet chemicals are purchased and used for specified purposes. Where use is specified and the desired outcomes achieved through specific instructions for safe use it is appropriate that this be recognised. As such the APVMA concurs with the Commission's assessment that retaining the existing exemption for appropriately labelled agvet chemicals does not undermine the objective of protecting workplace health and safety. In order for recommendation 6.3 to be adopted there may be a need for legislative amendment to provide recognition that the aims of existing OH&S laws are satisfied through the agvet labelling framework.

To realise a more seamless approach to labelling the APVMA believes that greater alignment between hazard-based and risk-based labelling systems can be achieved, facilitating a more logical and intuitive interface between hazard-based and risk-based labelling. Such alignment may be beneficial for label effectiveness, particularly with users of industrial and agvet chemicals. The APVMA has already commenced discussions with its advising agencies and with workplace OH&S regulators to explore and develop alignment opportunities.

The Commission's comments with respect to the future implementation of the Globally Harmonised System for Labelling (GHS) are noted. Alignment activities such as that mentioned above may be advantageous in terms of navigating the ultimate fit of the risk-based agvet labelling framework with the hazard-based GHS system. The Product Safety and Integrity Committee (PSIC) have established a working group to consider the implications of GHS for agvet chemicals. The GHS hazard classification system appears closely aligned to the existing Australian hazard classification framework (which applies to both industrial and agvet chemicals). There may be other potential opportunities for alignment in terms of the hazard and risk phrases used on risk-based agvet chemical product labels.

9 Draft Recommendation 8.1

The Environment Protection and Heritage Council (EPHC) Chemicals Working Group should continue to assess the need for a national framework for the management of chemicals in the environment.

If this work demonstrates that such a framework would improve effectiveness and efficiency, the Commonwealth, state and territory governments should negotiate an intergovernmental agreement to create an independent standard-setting body reporting to the EPHC.

- This body would develop standards for the environmental risk management of chemicals that the states and territories would adopt by reference, and have the power to ban or phase out chemicals, subject to appropriate cost–benefit analysis.
- Members of the environmental risk management standard setting body should be appointed based on their qualifications and experience. The body should be constituted to reflect the broader public interest and have the ability to appoint advisory bodies as necessary.

Comments:

The APVMA notes that the discussion in the draft report relating to the streamlining of environmental controls (underpinned by a Manual of Environmental Controls) with respect to the effectiveness and efficiency of the National Chemicals Environmental Management (NChEM) framework (page 218 of the draft report) relates to industrial chemicals. From the Commission's comments about the implementation of NChEM in this area, that risk management standard setting would be undertaken by a national body of experts with the Manual of Environmental Controls providing the basis for the standards (page 221 of the draft report), it is our understanding that draft recommendation 8.1 relates to the management of environmental risks of industrial chemicals.

The NRS for agvet chemicals has an extensive national framework to capture environmental information and input that information into regulatory decision-making for agvet chemicals – it is a national framework encompassing the environmental assessment and management of agvet chemicals (this was discussed in the APVMA's second submission to the study). In its comprehensive risk assessment process the APVMA

obtains advice from specialist environmental agencies, particularly DEWHA. In this respect the DEWHA sets standards for the environmental risk management of chemicals.

Once a product is registered if the registrant becomes aware of any information that may contradict the information provided for the assessment, or if available at the time of assessment may have lead to a different outcome, the registrant is required by the Agvet Code to provide that information to the APVMA. Additionally, the Adverse Experience Reporting Program (AERP) administered by the APVMA, provides a mechanism through which both government and the public can provide information about any adverse consequences related to the use of agvet chemical products. Where adverse or unacceptable environmental risks associated with legal agvet chemical use are identified the APVMA can use the reconsideration powers provided by the Agvet Code to mitigate those risks, or if this is not possible, to suspend or cancel product registration.

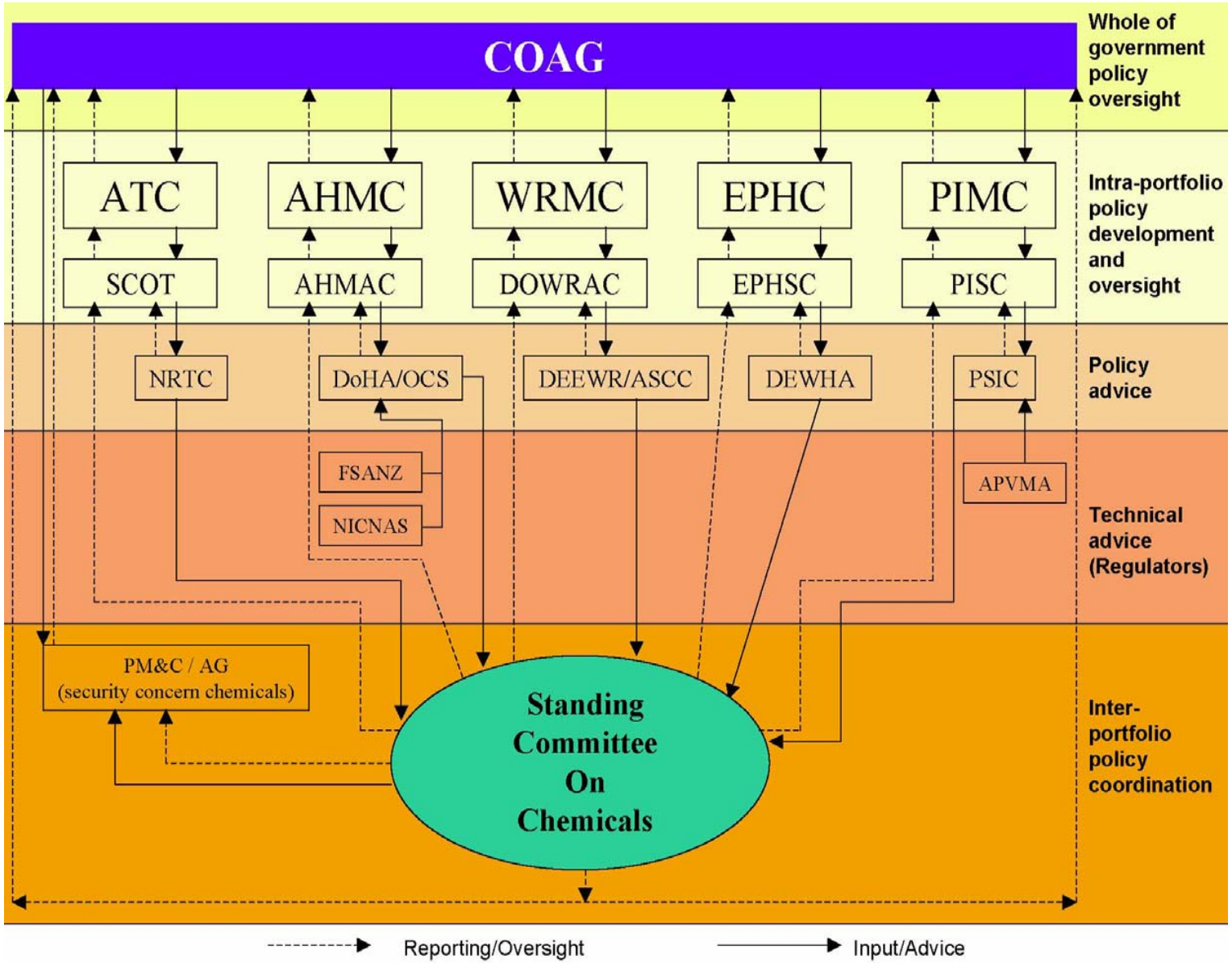
The NChEM agenda does not change or duplicate the APVMA's current consultation mechanisms, but rather will facilitate a more coordinated approach to feed environmental information through the existing channels. As such the APVMA is highly supportive of it. Efforts to enhance the existing mechanisms between state and territory environment protection agencies and the DEWHA aim to improve consultative arrangements in three of the key NChEM action areas, environmental risk assessment, information feedback and prioritising action. Such efforts will also work to ensure that the risk management standards determined by DEWHA remain relevant and enforceable at the state and territory level.

10 Conclusion

The APVMA supports the draft report and looks forward to participating in the reform activities following the release and consideration of the final report. We anticipate that many of the operational reform activities currently being progressed by the APVMA will complement the future reform agenda. The APVMA is committed to improving its regulatory efficiency and assisting the objective to minimise 'red tape' without compromising the overall policy objective of the NRS.

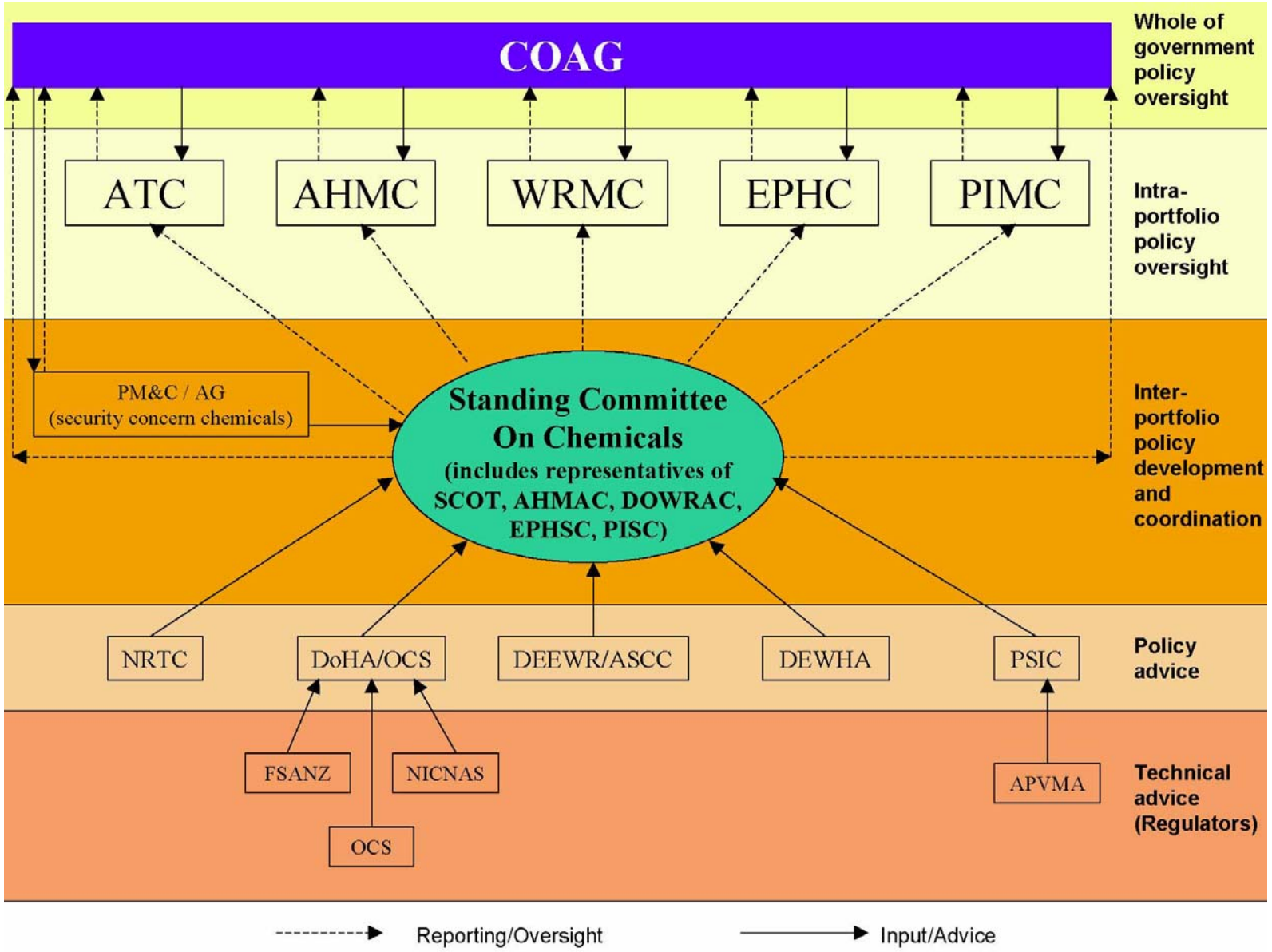
The APVMA looks forward to further discussing the draft report and matters relating to the regulation of agvet chemicals with the Commission.

MODEL 1 - DIAGRAMMATIC REPRESENTATION OF ORIGINAL APVMA PROPOSAL FOR A CHEMICALS COORDINATING COMMITTEE



Abbreviations: Attorney-Generals Department (AG), Australian Health Ministers Advisory Council (AHMAC), Australian Health Ministers Conference (AHMC), Australian Pesticides and Veterinary Medicines Authority (APVMA), Australian Safety and Compensation Council (ASCC), Australian Transport Council (ATC), Council of Australian Governments (COAG), Department of Education, Employment and Workplace Relations (DEEWR), Department of Health and Ageing (DoHA), Department of Prime Minister and Cabinet (PM&C), Department of the Environment, Water, Heritage and the Arts (DEWHA), Departments of Workplace Relations Advisory Committee (DOWRAC), Environment Protection and Heritage Council (EPHC), Environment Protection and Heritage Standing Committee (EPHSC), Food Standards Australia New Zealand (FSANZ), National Industrial Chemicals Notification and Assessment Scheme (NICNAS), National Road Transport Commission (NRTC), Office of Chemical Safety (OCS), Primary Industries Ministerial Council (PIMC), Primary Industries Standing Committee (PISC), Product Safety and Integrity Committee (PSIC), Standing Committee on Transport (SCOT), Workplace Relations Ministerial Council (WRMC).

MODEL 2 - DIAGRAMMATIC REPRESENTATION OF AN ALTERNATE MODEL FOR A CHEMICALS COORDINATING COMMITTEE



Abbreviations: Attorney-Generals Department (AG), Australian Health Ministers Advisory Council (AHMAC), Australian Health Ministers Conference (AHMC), Australian Pesticides and Veterinary Medicines Authority (APVMA), Australian Safety and Compensation Council (ASCC), Australian Transport Council (ATC), Council of Australian Governments (COAG), Department of Education, Employment and Workplace Relations (DEEWR), Department of Health and Ageing (DoHA), Department of Prime Minister and Cabinet (PM&C), Department of the Environment, Water, Heritage and the Arts (DEWHA), Departments of Workplace Relations Advisory Committee (DOWRAC), Environment Protection and Heritage Council (EPHC), Environment Protection and Heritage Standing Committee (EPHSC), Food Standards Australia New Zealand (FSANZ), National Industrial Chemicals Notification and Assessment Scheme (NICNAS), National Road Transport Commission (NRTC), Office of Chemical Safety (OCS), Primary Industries Ministerial Council (PIMC), Primary Industries Standing Committee (PISC), Product Safety and Integrity Committee (PSIC), Standing Committee on Transport (SCOT), Workplace Relations Ministerial Council (WRMC).