Australian Government
Australian Pesticides and
Veterinary Medicines Authority

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Chemicals and Plastics Regulation Study
Productivity Commission
LB2 Collins St East
MELBOURNE VIC 8003

CHEMICALS AND PLASTICS REGULATION STUDY

The APVMA welcomes the opportunity to further comment on this study and appreciated the opportunity to participate in the Commission's roundtable discussions on 11 and 12 December 2007.

The APVMA is pleased to provide supplementary submissions on labelling issues and environmental regulation.

Labelling

Duplication

The Australian labelling system for agricultural and veterinary (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. Attachment 1 explains the differences between hazard based and risk based labels. We have also attached a diagram of the two systems.

Currently the National Code of Practice for the Labelling of Workplace Substances[1] sets out the framework for the labelling of hazardous chemicals in the workplace. That Code was designed to be complementary to other pre-existing labelling systems and explicitly recognises the labelling system for agvet chemicals[2] as appropriate. The new draft National Code of Practice for the Labelling of Workplace Hazardous Chemicals released in December 2006 is intended to replace the existing Code of Practice but does not include similar complementary provisions.

If the new Code of Practice is adopted, any agvet chemical product other than those supplied and used only in the home will be subject to two labelling regimes. One labelling regime would dictate that all hazards relating to an unspecified use must be articulated on a product label and that workers would need to conduct a risk assessment of the intended use in accordance with a National Code of Practice. The other labelling regime would provide instructions to the worker on how and when to

[1] *National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]*.
[2] Agricultural chemical products are labelled in accordance with the *Code of Practice for Labelling Agricultural Chemical Products.* Veterinary chemical products are labelled in accordance with the *Code of Practice for Labelling Veterinary Chemical Products.*

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use the product and what restrictions and risk mitigation measures (including potential hazards of the specified use) to observe. We believe that this would potentially lead to confusion – simplicity and ease of understanding by the user facilitates labelling effectiveness.

The APVMA supports a seamless labelling system. However agvet chemicals are only registered for specified known uses and are intentionally applied to the environment and food. Consequently the outcomes (communication objectives) from agvet chemical labelling are distinguished 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.

APVMA Reform

To facilitate improved regulatory efficiency in labelling we are pursuing a range of reforms to our label approval processes that would allow registrants greater freedom to vary their labels without the need to seek prior approval from the APVMA. We consider that this reduction in regulatory requirements can be achieved without any compromise to environmental protection, public health or the protection of persons who use agvet chemical products. The essence of our reform proposal is to more clearly define the APVMA's "regulatory box" of label information. We do not believe that we add any value by "approving" on a label matters such as Dangerous Goods classifications covered by other legislation.

The reform proposal is presented in Attachment 2. It will give registrants the responsibility of updating the information included on agvet chemical product labels that is required by other legislation. We consider this to be a logical part of product stewardship.

Environmental Regulation

Monitoring

Prior to the registration of an agvet chemical the Agvet Code[3] requires, amongst other things, that the APVMA be satisfied that the use of the product would "*not be likely to have an unintended effect that is harmful to animals, plants or things or to* ***the environment***". In determining whether it may be satisfied from an environmental perspective, the APVMA undertakes a comprehensive risk assessment and obtains advice from specialist environmental agencies particularly the Australian Government Department of the Environment, Water, Heritage and the Arts (DEWHA).

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. These tools provide suitable information feedback mechanisms for the majority of chemical products regulated by the APVMA. However usage and monitoring data would be valuable to inform an effective performance measurement system for chemical

[3] *Agricultural and Veterinary Chemicals Code Act 1994.*

regulation outcomes. The APVMA is supportive of the proposed chemical monitoring database being developed by the DEWHA.

National Frameworks

The National Registration Scheme for agvet chemicals is established with an extensive national framework to capture environmental information and input that information into regulatory decision-making for agvet chemicals. The framework is represented diagrammatically in Attachment 3.

In developing the National Framework for Chemicals Environmental Management in Australia (NChEM), the Environment Protection and Heritage Council Chemicals Working Group in liaison with the APVMA has considered options for streamlining environmental input into APVMA processes. 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. Efforts to enhance the existing mechanisms between State and Territory Environment Protection Agencies and the DEWHA[4] aim to improve consultative arrangements in three of the key NChEM action areas, environmental risk assessment, information feedback and prioritising action. Other consultative mechanisms exist through State/Territory Co-ordinators[5], consultative forums and committees[6].

The APVMA looks forward to further participating in the study and discussing these matters with the Commission.

The APVMA contact for our input to this study is Dr John Paul (ph: 02 6210 4738 email: john.paul@apvma.gov.au).

Yours Sincerely,

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[4] The National Registration Scheme for agvet chemicals provides a national framework for chemicals management. The key area of NChEM activity within the National Registration Scheme is to strengthen the existing linkage between DEWHA and State environmental agencies. This is highlighted on the diagram in Attachment 3 by a bolded dashed line.

[5] The Agvet Code provides for a State/Territory Co-ordinator (a person designated by a Minister of the State or Territory) to co-ordinate input from State departments to the APVMA's decision-making process.

[6] The APVMA's consultative committees were discussed in the APVMA's initial submission to this study.

ATTACHMENT 1

Duplication in Labelling Regulation

The Issues Paper to this study notes that the case for regulating is dependent on both hazards and risks, with risk relating not only to hazard but also to the way in which a chemical product is used and thus the potential exposure to people and the environment. It states that hazard identification is an essential first step, but ideally chemical regulation aims to reduce risks to acceptable levels. The importance of risk management and communication, via mechanisms such as approved labels, to the protective function of regulation was highlighted in the APVMA's initial submission to this study.

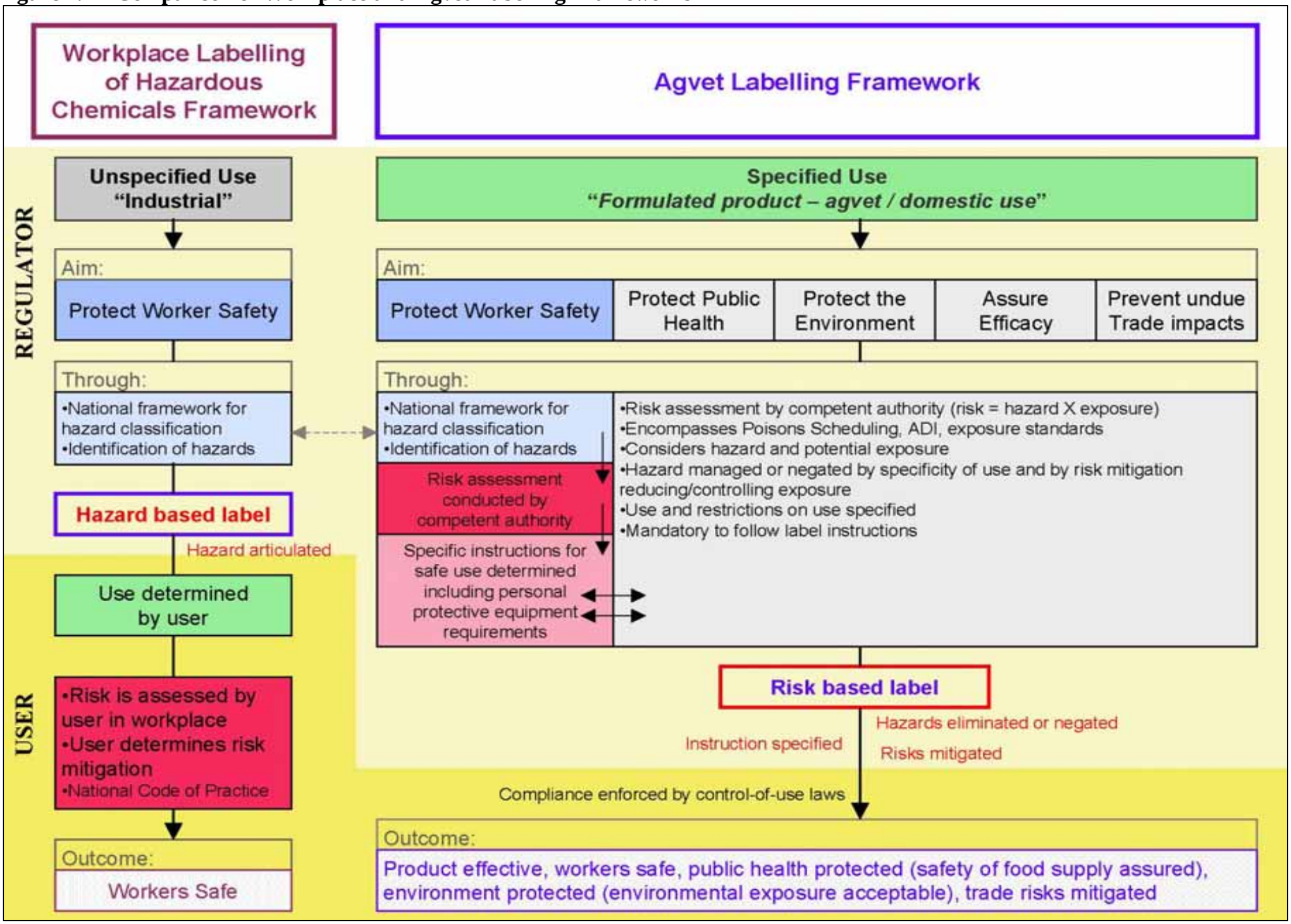
Where use is undefined and hence the potential exposure pathways are unknown or variable, hazard based labelling systems offer the most appropriate regulatory solution by flagging potential hazards to workers and the environment. These systems aim to manage the risks of exposure through raising the users' awareness of the hazards and permitting the user to assess the risks and take appropriate action. However where use is defined, risk based labelling systems offer greater regulatory effectiveness in terms of risk management and mitigation. These systems manage risks by providing specific instructions determined through expert scientific assessment of the potential risks associated with the authorised use. Figure 1.1 highlights the differing role of labelling in risk management between industrial chemicals for which the potential uses are undefined and formulated chemical products such as agvet chemical products for which the type and manner of use is specifically defined.

In contrast to industrial chemicals, agvet chemical products are only registered for use in defined situations by specified means. These parameters are set out in an approved label that contains appropriate instructions for use, precaution statements and other information necessary for the safe and effective use of the agvet product. Approved labels also include hazard information such as Poisons Scheduling and Dangerous Goods Classification that is specific to the product. For highly hazardous products Poisons Scheduling restricts their supply. Where the risks of use of a product are such that specific operator skills are necessary the existing legislative framework also allows for the supply and use of those products to be restricted to authorised persons. The current labelling system for agvet chemicals provides a framework for both the communication of hazards and risks, as well as risk management through specific use instruction.

In relation to worker safety, the hazard classification methodology is the same in both labelling systems. The worker safety assessment in the agvet scheme is fully compliant with the occupational health and safety (OH&S) hazardous substances standards. However in the agvet system where use is specified the risk assessment is conducted by a competent authority rather than by the user in the workplace and instructions for safe use determined and specified on the label rather than being determined by the user. Although the aim of both systems is worker safety, the risk-based label provides a more advanced level of protection than a hazard-based label as specific instructions mitigate the risks of use to acceptable levels.

Worker safety assessments for agvet chemical products are highly sophisticated as they consider matters such as frequency of use and the potential for chronic and acute exposure. A worker using an agvet chemical product in accordance with the label instruction is guaranteed compliance with all relevant OH&S standards. For this reason the APVMA believes that the risk based labelling system for agvet chemicals should be recognised by the *Draft National Code of Practice for the Labelling of Workplace Hazardous Chemicals* as being appropriate for agvet chemicals used in the workplace which includes farms.

Figure 1.1 – Comparison of Workplace and Agvet Labelling Frameworks



ATTACHMENT 2

APVMA Labelling Reform Proposal

The labelling provisions of the Agvet Code and the Agvet Code Regulations[7] are broad and all encompassing. In approving a label the APVMA is required to determine the particulars that are to be contained on the label and obtain a copy of the label in the form that it will be presented to the marketplace. The effect of these provisions is that the APVMA effectively "approves" matters that are not specifically within its regulatory scope. The APVMA believes that its quasi-approval of matters outside its jurisdiction by virtue of the fact that they are required by other legislation to be included on a label is duplicative and unnecessary.

Approved labels generally contain three broad elements of information:

1. Information required by the APVMA, namely the instructions it determines and other matters that the Agvet chemical legislation requires to be included on labels;
2. Information required by other legislation but not controlled by the APVMA such as Poisons Scheduling and Dangerous Goods Classification[8]; and
3. Information that the registrant, for commercial reasons, requires to appear on the label such as logos and warranty information.

Under the current arrangements the APVMA has found that in practice the distinction between these key elements is often blurred, particularly in terms of whether regulatory approval is or should be required to change them on a label. This has the potential to impose a burden on registrants as it ultimately means that the APVMA receives applications to alter labels where no risk assessment is required. Applications to update a Dangerous Goods classification is a prime example.

To reduce this burden, as part of the APVMA's ongoing labelling reform agenda the APVMA is working to pursue the establishment of a clear hierarchy to distinguish the mode of regulatory approval for these key label elements. Under the proposed hierarchy APVMA required information would be controlled by application to the APVMA, information required by other legislation would be controlled by condition of label approval[9], and registrant desired information would be controlled by permit.

The proposal as presented diagrammatically in Figure 2.1 would effectively broaden the type of changes that could be made to product labels without application to the APVMA[10]. In particular it would streamline the process of updating the information included on agvet chemical product labels that is required by other legislation.

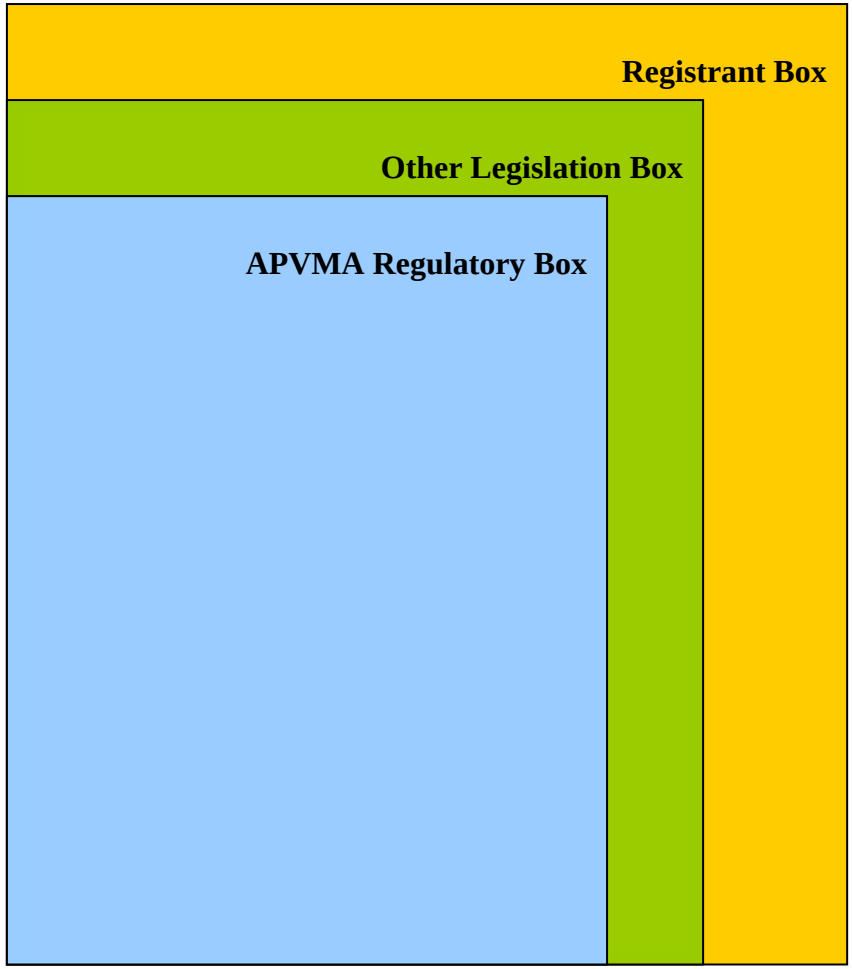
[7] *Agricultural and Veterinary Chemicals Code Regulations 1995.*

[8] These matters are regulated by other authorities and addressed by Acts other than the Agvet Code.

[9] Such a condition would require registrants to maintain labels in line with the contemporary requirements of that other legislation.

[10] As noted in Section 8.1 of the APVMA's initial submission to this study two permits are currently issued (PER6868 and PER9523) to allow a number of administrative changes to labels and certain variations with respect to net contents to be made without application to the APVMA.

Figure 2.1 - APVMA Labelling Reform Proposal



Registrant Box

- Any other matters that registrant places on label for commercial reasons
  eg. Logo
  Warranty

Control by Permit

Other Legislation Box

- Matters that other legislation requires to appear on label but which are not controlled by APVMA
  eg. Poisons Scheduling
  Dangerous Goods Classification

Control by condition

APVMA Regulatory Box

- Instructions determined by APVMA
- Matters that Agvet legislation says must appear on label and which are determined by APVMA

Control by application to the APVMA

ATTACHMENT 3

National Framework (Environment) of the Agvet National Registration Scheme