Regulatory Impact Statement

Proposed *Agricultural and Veterinary Chemicals (Control of Use) Regulations 2017*

Prepared by Jaguar Consulting Pty Ltd

Economic Development, Jobs, Transport and Resources

AGRICULTURE VICTORIA

SUMMARY

The *Agricultural and Veterinary Chemicals (Control of Use) Regulations 2007* ("the current regulations") are due to sunset on 24 July 2017. The Department of Economic Development, Jobs, Transport and Resources (the Department) has developed the proposed *Agricultural and Veterinary Chemicals (Control of Use) Regulations 2017* ("the proposed regulations") to replace the current regulations with limited amendments. For the most part, these changes constitute amendments to the detail of existing requirements. Proposed changes include:

- Rationalised agricultural chemical use record keeping requirements to align with agreed nationally consistent minimum agricultural chemical record keeping standards. This includes a small reduction in the number of elements, improved flexibility for making records and removal of the unused exemption for approved quality assurance programs.
- Folding into the more general provision for records of the use of veterinary chemicals, the currently separate provision to record the use of hormonal growth promotants and also the removal of the unused exemption for approved quality assurance programs.
- Improved criteria when a veterinary chemical label or advice note is required and the inclusion of requiring 'the batch number and expiry date (if known)' to be included on a label or advice note.
- Improved clarification of requirements for land occupiers, employees and contractors to provide notification where there is a sensitive service within 200m of the land to be sprayed.
- Adding and prescribing a fifth way to comply with existing aerial spraying equipment requirements.
- The prescribed reason for testing of potentially contaminated stock and agricultural produce to be conducted at the owner's expense to a lower 'reasonable suspicion' standard or where they have been found guilty of prescribed offences.
- Transferring requirements relating to the use of the of 'restricted use' agricultural chemicals from Orders in Council to the proposed regulations will enable the Australian Pesticides and Veterinary Medicines Authority (APVMA) to issue permits for 'off label' use of these chemicals in Victoria.
- The proposed changes will also require the remaking of the two Orders in Councils that currently include restrictions on off label use. New Orders in Councils will be made that include changes to improve the regulation of sodium fluoroacetate (1080) and 4-aminopropiophenone (PAPP), remove the prohibition on the use of grain-based perishable pest animal baits containing 1080 for the control of feral pigs subject to permit or label directions and remove licencing and permit exemptions for 'restricted use' chemicals under accredited quality assurance programs in specific circumstances.

The only substantive new provision proposed to be adopted is a prohibition on the possession of certain unregistered agricultural chemicals that pose a greater risk of misuse, particularly for poisoning of animals.

The current regulations constitute the main regulations made under the authority of the *Agricultural and Veterinary Chemicals (Control of Use) Act 1992* (the Act), which is the primary legislation controlling the use of these chemicals in Victoria. Importantly, however, the regulatory structure surrounding agricultural and veterinary chemicals also includes a substantial element of national legislation.

The body of Federal and state legislation of agricultural and veterinary chemicals collectively covers the assessment, approval, registration and use of these chemicals, with the role of state governments essentially being focused on the latter area. The scope of the regulatory controls imposed is similar to that found in most Organisation for Economic Co-operation and Development (OECD) countries.

While agricultural and veterinary chemicals make a very substantial contribution to overall agricultural productivity, significant risks are entailed in their use. These risks take several forms, as follows:

- risks to the health of persons, including chemical users, those exposed to environmental contamination and those exposed to contaminated produce;
- risks to the health of animals (including both stock and native animals), stock and the broader environment; and
- risks to the access of the agricultural sector to domestic and, in particular, export markets.

As discussed in this RIS, the potential size of the harms associated with these risks is substantial and there is, consequently, a strong case for a comprehensive set of regulatory interventions in this field. Such interventions have been in place for many decades and are adopted in all comparable countries.

Benefits

The key provisions of the existing and proposed regulations and their expected benefits are as follows:

- requiring a range of parties to record the sale and use of chemicals, which greatly facilitates the investigation of incidents by the relevant authorities, thus contributing to more effective and timely responses to harms that arise in connection with the use of these chemicals;
- specifying labelling requirements, which helps to ensure that chemicals are reliably identified and appropriately used and thus contribute to a reduction in the incidence of harms due inadvertent misuse;
- specifying provisions in relation to the use of aerial spraying, which helps to prevent "spray drift" and the associated potential for persons, stock and produce to be inappropriately exposed to chemicals;
- specifying notification provisions in relation to aerial spraying and the use of misting devices, which serves the "right to know", as well as enabling those likely to be sensitive to chemical exposure to take any additional avoidance measures they deem appropriate; and
- prohibiting the possession of any of a specified list of dangerous, unregistered chemicals, which is intended to minimise harms due to the deliberate or inadvertent use of these chemicals by those who hold stocks of previously registered chemicals.

In sum, the current and proposed regulations contribute to the reduction of the harms potentially associated with the use of agricultural and veterinary chemicals in a wide range of contexts. In most cases, they are closely linked with other legislative provisions at Federal and/or State level.

Costs

The incremental costs associated with the proposed regulations have been estimated to be equal to approximately $3.5 million per annum, which is equivalent in present value terms to a total cost of $28.3 million[1] over the expected 10 year life of the regulations.

It has not proven possible to quantify the specific benefits provided by the current regulations. This reflects, in part, the fact that many of the benefits involved, such as the prevention of harms to native species, are difficult to quantify in dollar terms. It also reflects the closely interwoven nature of these regulations and the wider regulatory structure.

That said, even a small number of incidents of contamination of stock or produce can give rise to substantial economic costs due to the potential for restrictions to be placed on the access of producers to markets. Several elements of the current and proposed regulations provide specific tools to assist in addressing the problem of contamination, thus minimising risks to market access. Moreover, to the extent that the regulations contribute to the safeguarding of human health, the Department considers that the annual costs identified above are most likely to be more than offset by benefits[2].

Given these factors, the Department is confident that the benefits conferred by the current and proposed regulations exceed the identified costs.

A further perspective on this issue is consideration of the proportionality of the costs identified. As discussed below, the benefits to agriculture arising from the use of these chemicals, from a Victorian perspective, are likely to be of the order of $2.9 billion per annum. The identified costs represent slightly more than 0.1% of this total. A second approach to the question of proportionality lies in comparing the identified costs with the number of licence and permit holders. There are 21,400 licence and permit holders in Victoria, suggesting an average cost of the proposed regulations of $163.55 per licence and permit holder. The Department considers this to be a modest total, given the importance of these chemicals to most or all of this group. Moreover, it should be underlined that many users of agricultural and veterinary chemicals are not licence and permit holders and that the beneficiaries of regulation in this field extend far beyond this group.

In light of these considerations, the Department believes that the expected benefits of the proposed regulations will substantially outweigh the identified costs.

[1] Using a 4% real discount rate.

[2] Noting, in particular, that a standard Value of a Statistical Life (VSL) exceeds $4 million.

Feasible alternatives

Given the extent to which the existing and proposed regulations are closely interwoven with other state and Federal legislation, the range of feasible alternatives to the proposed regulations which can be identified is necessarily narrow. The general approach to the regulation is clearly established in inter-governmental agreements and in the Act. Thus, the alternatives identified essentially constitute specific variations to the content of the proposed regulations which have been given consideration by the Department during the course of the development of the proposed regulations, and this RIS, but have ultimately been rejected. In sum, these were:

Adopting a performance-based requirement in relation to spray-drift management

Consideration was given to the option of replacing the current, prescriptive requirements in this area with a performance standard, along the following lines:

"A pilot must ensure that he/she has sufficient information regarding wind speed and direction at the time that spraying is conducted to enable him/her to ensure that spray drift is avoided."

To the extent that the industry is able to identify new and more effective and/or lower cost means of obtaining the required information during the life of the proposed regulations, adopting a performance-based requirement could yield substantive cost savings, vis-à-vis the proposed specification of several specific information-gathering mechanisms. However, advice received from the aerial spraying industry is that the current regulatory requirements, supplemented by the proposed additional compliance option, will not impose any incremental cost burden on its members. Given this, there do not appear to be significant opportunities for cost savings to be realised through the adoption of a performance-based regulatory requirement.

Removal of the notification requirement in respect of aerial spraying

The notification requirement, which was first adopted in 2007 is arguably unnecessary, given the other specific requirements in place as part of the regulations to minimise the risk of spray drift and the relatively low and constant number of spray drift related investigations undertaken in recent years. However, available evidence indicates that the costs of this notification requirement have been found to be modest in practice (totaling less than $2,500 per annum) while, conversely, it is considered likely that the existence of this notification requirement provides significant public confidence benefits, notably through the provision of the opportunity for sensitive populations to take steps to further reduce their risk of exposure to chemicals in this context.

Adoption of compulsory reporting of contaminated produce by laboratories

Consideration was given to the possibility of adopting a compulsory reporting requirement, as this would potentially increase the likelihood that regulators have become aware of incidences of contamination as well as potentially ensuring that such notifications would occur in a more timely fashion, thus facilitating a more timely and effective response. To the extent that these benefits are available, the risk of costs being incurred in terms of denial of access to export markets, in particular, would be expected to be reduced.

Conversely, however, it was noted that a national requirement for compulsory reporting is currently under development and that the implementation of a state based system in advance of the adoption of this national approach is likely to be less effective in practice and, potentially, to give rise to certain uncertainties as to duties as well as distortions within the marketplace.

Consequently, it was determined not to proceed with this proposal pending further progress being made on the proposed national notification requirement.

Adopt a general prohibition on the possession of unregistered AgVet chemicals

An alternative approach to the proposed prohibition on the possession of certain, specified unregistered AgVet chemicals would be to broaden the proposed prohibition to include all unregistered AgVet chemicals. Adopting a generalised prohibition on the possession of unregistered AgVet chemicals could yield additional harm reduction benefits by removing a greater range of chemicals from circulation. That said, DEDJTR has little available information as to the frequency and extent of harms arising from the misuse of unregistered AgVet chemicals. Thus, it is difficult to determine to what extent this option would provide additional benefits in practice.

Conversely, the costs of adopting a broader prohibition were considered to be potentially much larger than those of the more targeted approach proposed. Whereas it was estimated that the partial prohibition contained in the proposed regulations is likely to impose a one-off compliance cost of around $5,000, the total prohibition option could lead to one-off disposal costs in the range of $50,000 - $100,000. DEDJTR considers that, in light of the existing regulatory requirements and incentives such the industry ChemClear program, a selective approach to this issue constitutes the more proportionate approach to risk management. However, stakeholder views are sought on this issue.

Stakeholder input

The Department seeks advice from stakeholders on the proposed regulations and the associated costs and benefits. In particular:

- Are the assumptions used in calculating the associated costs broadly accurate and if not, what alternative estimates would be appropriate?
- What proportion of activities such as record keeping would occur for reasons other than compliance with the regulations?
- Would it be appropriate to move to performance-based requirements in relation to aerial spraying rather than prescriptive requirements for notification and equipment?
- Should compulsory reporting of contaminated produce be adopted nationally or unilaterally by Victoria?
- Are there additional chemicals that should be included in the proposed prohibition on the possession of unregistered AgVet chemicals or should this be expanded to include all unregistered AgVet chemicals?

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1. INTRODUCTION

1.1. Overview

Purpose of this Regulatory Impact Statement (RIS)

Consistent with the operation of the *Subordinate Legislation Act 1994*[3], the *Agricultural and Veterinary Chemicals (Control of Use) Regulations 2007* ("the current regulations") are due to sunset on 24 July 2017. The proposed *Agricultural and Veterinary Chemicals (Control of Use) Regulations 2017* ("the proposed regulations") are intended to replace the current regulations with limited amendments. This RIS describes the role of the regulations within the broader context of the regulation of agricultural and veterinary chemicals; identifies the policy problems they address, considers the options available to address these problems and assesses the benefits and costs of these options from the perspective of society as a whole. It is intended to inform stakeholders and is being released as part of a consultation process open to all stakeholders and the general public.

Agricultural and Veterinary Chemicals Definitions

Agricultural and Veterinary Chemicals (AgVet Chemicals) are defined in the Agvet Code[4], as follows:

Definition of agricultural chemical product

A substance or mixture of substances that is represented, imported, manufactured, supplied or used as a means of directly or indirectly:

- destroying, stupefying, repelling, inhibiting the feeding of, or preventing infestation by or attacks of, any pest in relation to a plant, place or thing
- destroying a plant
- modifying the physiology of a plant or pest so as to alter its natural development, productivity, quality or reproductive capacity
- modifying an effect of another agricultural chemical product, or
- attracting a pest for the purpose of destroying it.

An agricultural chemical product includes a substance or mixture of substances declared by the AgVet Code Regulations to be an agricultural chemical product.

An agricultural chemical product does not include:

- a veterinary chemical product, or
- a substance or mixture of substances declared by the AgVet Code Regulations not to be an agricultural chemical product

Definition of a veterinary chemical product

A substance or mixture of substances that is represented as being suitable for, or is manufactured, supplied or used for, administration or application to an animal by any means, or consumption by an animal, as a way of directly or indirectly:

- preventing, diagnosing, curing or alleviating a disease or condition in the animal or an infestation of the animal by a pest; or
- curing or alleviating an injury suffered by the animal; or
- modifying the physiology of the animal:
  - (i) so as to alter its natural development, productivity, quality or reproductive capacity; or
  - (ii) so as to make it more manageable;
- modifying the effect of another veterinary chemical product.

A veterinary chemical product includes:

- a vitamin, a mineral substance, or an additive, if, and only if, the vitamin, substance or additive is used for a purpose mentioned in paragraph (2)(a), (b), (c) or (d); and
- a substance or mixture of substances declared by the regulations to be a veterinary chemical product.

A veterinary chemical product does not include a substance or mixture of substances that is:
(i) prepared by a pharmacist in accordance with the instructions of a veterinary surgeon; or
(ii) prepared by a veterinary surgeon; in the course of the practice, by the person preparing the substance or mixture of substances, of his or her profession as permitted by or under a law of this jurisdiction; or
(iii) a substance or mixture of substances declared by the regulations not to be a veterinary chemical product.

[3] The Act provides that all Victorian regulations are automatically repealed 10 years after coming into force, unless sooner repealed.
[4] Agricultural and Veterinary Chemicals Code Act 1994 (Cth)

The Regulatory Environment

In Victoria, there have been legal controls over the sale of agricultural and veterinary chemicals since the *Fungicides Act 1916,* which placed controls on the composition and labelling of fungicides. The regulatory framework has evolved over time and now includes both federal and state legislation which collectively covers the assessment, approval, registration and use of these chemicals. The scope of the regulatory controls imposed is similar to that found in most Organisation for Economic Co-operation and Development (OECD) countries. The following describes the key regulatory arrangements of the national chemical regulatory environment and how Victoria fits into this framework.

Under the Australian regulatory framework, the Australian Pesticides and Veterinary Medicines Authority (APVMA) leads the regulation of agricultural and veterinary (AgVet) chemicals up to the point of retail sale, while state and territory governments are responsible for controlling the use of agricultural and veterinary medicines beyond the point of retail sale. These arrangements were formalised in a 2013 intergovernmental agreement on the evaluation, registration and control of agricultural and veterinary chemical products[5].

In Victoria, the primary legislation regulating agricultural and veterinary chemicals is the *Agricultural and Veterinary Chemicals (Control of Use) Act 1992* (the Act) and its associated regulations. The Act is administered by Department of Economic Development, Jobs, Transport and Resources (DEDJTR).

The role of the Australian Pesticides and Veterinary Medicines Authority (APVMA)

The APVMA is an Australian government statutory authority within the portfolio of the Minister for Agriculture. It operates a system to register and approve active constituents, chemical products and product labels and to issue permits.

In 1995, the Commonwealth Government assumed responsibility for all agricultural and veterinary chemicals up to and including point of sale or supply from the States and Territories. This responsibility was to be administered by the National Registration Authority for Agricultural and Veterinary Chemicals (now the APVMA).

The APVMA assesses applications from chemical companies and individuals seeking registration, which is a precondition for them to be able to supply their product to the marketplace. Applications are assessed by the APVMA's scientific staff, during which process they may also be referred to other relevant scientific organisations, Commonwealth and state agriculture departments for advice. The APVMA does not generate product safety and efficacy data itself, rather it assesses applications based on the data provided to it by applicants.

The APVMA will approve and register an agricultural or veterinary chemical product if the scientific data and assessment finds:

- The product works as intended (i.e. it is effective); and
- The instructions for use included on the proposed product label are consistent with good agricultural practice and the product will, if used in accordance with those instructions, have no harmful or unintended effects on people, animals, the environment or international trade (i.e. it is safe).

Product labels and Maximum Residue Limits

Product labels are developed by the applicant for registration of the chemical product, using APVMA specifications. Labels give directions on the safe and effective use of the product and state and territory governments may require that the product be used in accordance with these instructions.

The registration process results in the setting of a Maximum Residue Limit (MRL) for the active constituent in commodities associated with the proposed use pattern. If the MRL is exceeded, this is an indicator that the use of the product was not consistent with Good Agricultural Practice.

[5] See: http://www.agriculture.gov.au/ag-farm-food/ag-vet-chemicals/domestic-policy/history-of-coag-reforms/iga-coag

Chemical use practices and community concerns

AgVet chemicals are widely used in primary production systems. However, AgVet chemical use practices are continually evolving, with numerous factors influencing what and how chemicals are used. These include:

- Chemical access – Chemical products are added or removed from the market, at both producer and regulator initiative. Newer products often have more restricted or narrower use patterns.
- Seasonal factors – Pest pressures placed on farmers are dynamic and strongly influenced by environmental conditions e.g. wet periods with high humidity increase the use of fungicides and lice infestations in cattle build up over autumn and winter.
- Industry standards – Quality Assurance programs can dictate to growers what chemicals are permitted to be used.
- Market access requirements – Export markets may have different MRLs for AgVet chemicals from those established in Australia.

As a result, maintaining the integrity of the regulatory framework is crucial to ensuring the continuing availability of these chemicals and provides assurance to the public of the government's commitment to their health and safety and the protection of agriculture and the environment.

The economic importance of agricultural and veterinary chemicals

Agricultural and veterinary chemicals constitute a highly important input to the agriculture sector, substantially increasing overall productivity in a wide range of areas. A 2013 Deloitte Access Economics[6] report commissioned by industry body CropLlife Australia[7] estimated that, at a national level, $17.6 billion worth of agricultural produce is attributable to the use of agricultural chemicals (called "Crop Protection Products" (CPP) in the report). This was said to be equal to 68% of the total annual value of crop production[8]. This suggests that agricultural output is around three times as high as it would be in the absence of CPPs. The Deloitte report also estimates that there is $0.84 of (direct and indirect) value added in the economy for each dollar of agricultural output. Thus, the total economic value added due to the use of agricultural chemicals is around ($17.6bn x 0.84) = $14.8 billion.

According to the ABS[9], the value of crop production in Victoria in 2014-15 was $5.0 billion. If the above ratios from the Deloitte report are applied, it suggests that CPPs are responsible for:

- $5.0 billion x 68% = $3.4 billion in crop production; and
- $3.4 billion x 0.84 = $2.9 billion in value added.

Conversely, the Federal Department of Agriculture and Water Resources has estimated that expenditure on agricultural and veterinary chemicals accounts for 17% of all farm costs[10].

Thus, agricultural chemicals are a fundamental input to the farm sector and yield major benefits to the economy. Conversely, significant risks attend their use. The nature and extent of these risks requires substantial regulatory intervention to ensure that users have access to safe and effective chemical products and adequate advice as to their use, via approved label directions and that the general population and environment are protected from toxic exposures to AgVet chemicals. In sum, restrictions are placed on the use of these chemicals in order to:

- protect the health of both the general public and chemical users;
- protect the environment;
- protect the health and welfare of farm animals;
- protect the domestic and export trade in agricultural products and livestock; and
- protect against financial loss caused by damage to plants and stock from agricultural spraying

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[6] Deloitte Access Economics (2013). *Economic Activity Attributable to Crop Protection Products***.** CropLife Australia.

[7] CropLife is the peak national industry organisation representing the agricultural chemical and biotechnology (plant science) sector in Australia.

[8] The use of veterinary chemicals is also widespread and a major contributor to the productivity of the livestock industry. However, no equivalent productivity measures have been identified in relation to this sector.

[9] ABS Cat: 7503.0, Value of Agricultural Commodities Produced, Australia, 2014-15.

[10] http://www.rirdc.gov.au/docs/default-document-library/nri-project-chemical.pdf?sfvrsn=2

1.2. Description of the current regulations

The Agricultural and Veterinary Chemicals (Control of Use) Act (the Act)

The Act is the major piece of State legislation through which agricultural and veterinary chemicals are regulated in Victoria. It has been in effect since 1996 and imposes controls in relation to:

- the use, application and sale of agricultural and veterinary chemical products, fertilisers and stock foods;
- agricultural spraying, whether undertaken from the ground or the air;
- agricultural production, to prevent the contamination of food intended for human consumption; and
- the transport, handling, sale and other dealings with agricultural chemicals, fertilisers and stock feed.

The Act also enables the Minister to fix fees and charges for the issue of licences and permits.

The current regulations

The current regulations constitute the main subordinate legislation established under the Act and the following provides an overview of their content. The current regulations include the following provisions:

Recording of chemical use

Regulation 5 requires the user of an agricultural chemical to record details of that use within 48 hours. These include the product used, amount applied, context in which it was used (e.g. the crop), specific location at which it was applied and the name and contact details of the person who applied the chemical.

Regulation 6 establishes similar requirements in relation to the use of veterinary chemicals. It requires the species, location and identification of each animal treated to be recorded, together with the dates of initial and subsequent treatments and the dosages used.

Regulation 7 establishes equivalent requirements for veterinary practitioners. Records must include the name of the product used or sold, to whom it was sold, the directions for use, concentration or form in which it was used, amount of the product sold, species and number of animals to be treated and their location. In the case of unregistered chemicals, the active constituent must be identified. The scope of this requirement covers all veterinary chemicals that contain a schedule 4 poison[11].

In each case, the required records must be retained for two years.

Labelling requirements - veterinary chemicals

Regulation 8 requires veterinary practitioners who sell veterinary products to provide a label or advice note to the purchaser which contains information including the species and type of animal (i.e. the breed, age and sex) to be treated, the directions for the treatment of the animal(s), the withholding period for the treated animal (if applicable) and the date on which the product was supplied.

Regulation 9 provides that the withholding period, referred to in regulation 8, must be no less than that issued by the manufacturer of the product and approved by the APVMA. Where an unregistered product or an APVMA approved product is sold with instructions from the veterinary practitioner that differ from the directions from the APVMA approved label, the specified withholding period must meet the same objective – i.e. that of ensuring that the treated animal will not be contaminated at the end of the withholding period.

Regulation 10 sets out offences in relation to the labelling requirements established by regulations eight and nine.

Recording requirements – hormonal growth promotants

Regulation 11 establishes recording requirements for the use of hormonal growth promotants (HGPs), which must be met within 24 hours of application. The specific requirements are similar to those established by regulations 5 and 6, and include the details of the supplier of the hormone, the animals on which they were used, the property on which they were used, amounts used and the amount of the product lost or damaged during application.

[11] As in accordance with Schedule 4 of the *Drugs Poisons and Controlled Substances Act 1981*

Agricultural spraying

Regulation 12 establishes a requirement for a land owner or occupier causing agricultural chemicals to be sprayed on his/her land by means of an aircraft or mister[12] to first notify the management of any school, hospital or aged care facility located within 200 m of the land on which the chemical is to be sprayed of the proposed date, time and duration of the spraying.

Regulation 14 states that aerial spraying can only be carried out in one of the following circumstances:

- if a smoke generating device is used at ground level near the point of spraying immediately before and during the spraying;
- if the aircraft is equipped with a smoke generating device that is operated immediately before and during the spraying;
- if a windsock at ground level is clearly visible to the pilot immediately before and during spraying; or
- if an automatic weather station is operating near the point of spraying and the pilot has access to information from it as to wind speed and direction immediately before and during spraying.

Chemicals requiring a licence for commercial use

Section 30 of the Act provides that a person must not carry on business or offer a service for fee or reward which involves the use of any "prescribed chemical products" unless they hold a Commercial Operator Licence. Regulation 13 establishes that any agricultural chemical constitutes a prescribed chemical product for the purposes of this section of the Act.

Testing of stock or produce at the expense of the owner

Section 56 of the Act provides that an authorised officer can require stock or agricultural products to be tested, in certain circumstances, and that such testing may be carried out at the expense of the owner in prescribed circumstances.

Regulation 15 establishes that the prescribed circumstances are that the owner has been convicted of an offence under one of various specified sections of the Act or of the *Drugs, Poisons and Controlled Substances Act 1981* or its regulations or that the owner has sold or consigned for slaughter contaminated stock or agricultural produce in the last two years.

Grounds for refusal to grant a licence or permit

Section 3 of Schedule 1 of the Act empowers the Chief Administrator to refuse an application for a licence or permit on "any prescribed ground". Regulation 16 establishes that the prescribed ground is that the Chief Administrator believes that the applicant has not completed the approved course of training in relation to that application.

2. NATURE AND EXTENT OF THE PROBLEM

As noted in section 1, the current regulations address three , inter-related risks arising from the use of agricultural and veterinary chemicals. These are risks to:

- the health of the general public and chemical users;
- the health of native flora and fauna, crops and farm animals; and
- the domestic and export trade in agricultural products and livestock.

The following discussion provides data on the nature and extent of each of these risks including residual risks that remain following the current regulatory controls to address these risks. The discussion also outlines rationale for regulatory intervention.

2.1. Risks to human health

Many agricultural and veterinary chemicals contain highly toxic ingredients. This means that exposure to these chemicals can cause poisoning and even death. The effects of acute poisoning can include abdominal pain, dizziness, headaches, nausea, vomiting and skin and eye problems. Chronic effects can include respiratory problems, memory disorders,

[12] A mister is a spraying device that is capable of spraying fine droplets, which are more likely to give rise to give rise to concerns regarding spray drift, and is generally ground-based.

dermatological problems, depression, neurological deficits, cancer and birth defects. Death can result from either acute or chronic exposure.

Even in the context of a multi-level regulatory system, the incidence of exposures[13] to agricultural and veterinary chemicals recorded by the Victorian Poisons Information Centre (VPIC) remains a significant issue, as shown in table 2.1.

Table 2.1: Recorded exposures to agricultural and veterinary chemicals 2014-15

Category	Number
Baits	368
Herbicides	457
Insecticides	639
Fungicides	17
Other chemicals	117
Veterinary products	445
Total	**2043**

Source: VPIC Annual Report 2015, pp 28-29

Table 2.1 shows that 2043 exposures were recorded in 2014 – 15. This represents a 13% reduction from the 2371 exposures recorded in the same source in 2005. Nonetheless, it indicates that exposure to these classes of chemicals remains common in Victoria.

A more specific data source in relation to adverse effects on human health due to the use of AgVet chemicals is the APVMA, which in 2014 (the most recent year for which data are available) assessed 135 reports relating to adverse experiences from registered veterinary medicines and agricultural chemicals involving effects on human health. Of these, 21 were classified as probable or possible, 99 as off-label (i.e. due to chemicals use contrary to label instructions) and 15 as unlikely or unknown.

As noted above, these adverse experience reports broadly relate to the use of approved veterinary medicines and agricultural chemicals within the context of compliance with the existing regulatory requirements. Thus, they constitute examples of the "residual risk" associated with the use of these medicines and chemicals. By implication, substantially greater harms would be expected in the context of an unregulated environment in relation to the use of these substances.

A third data source is provided by Worksafe Victoria. Table 2.2, below, is reproduced from the most recent WorkSafe Victoria Statistical Summary and provides a breakdown of WorkCover claims by mechanism of injury, for the 10 years to 2011 – 12. Consistent with the above data from the VPIC, this shows that the incidence of workplace injury claims due to exposure to chemicals and substances has demonstrated a long-term decline, with the most recent figure of 232 being 46% lower than the 2002 – 03 figure. This decline stands in contrast to the overall trend in the workplace injury compensation claims, which shows a much smaller decline, of only 9%, over the same period.

More detailed information regarding the underlying causes of this declining trend in chemical exposure claims is not available. However, this data suggests that the system of regulation of chemical use, of which the current regulations form a part, has demonstrated a quite high level of effectiveness over the past 15 years at least. Again, however, it is clear that only a subset of the chemical exposure claims reported in table 2.2 would relate to agricultural chemicals.

[13] The VPIC provides information to people concerned about having been exposed to a poison. It states that "VPIC aims to prevent unnecessary visits to general practitioners and hospitals and unnecessary ambulance callouts, and to ensure patients who are poisoned or envenomed receive the most appropriate treatment promptly."(VPIC Annual Report (2015), p3). An "exposure", as recorded in the VPIC Annual Report represents a call from a member of the public concerned that they have been exposed to a poison and seeking VPIC advice. An exposure therefore does not necessarily entail poisoning, in the sense of an adverse consequence occurring due to exposure to the chemical.

Table 2.2: Workplace injury compensation claims by agent of injury

Mechanism of injury	**Report year**									
	2002-2003	*2003-2004*	*2004-2005*	*2005-2006*	*2006-2007*	*2007-2008*	*2008-2009*	*2009-2010*	*2010-2011*	*2011-2012*
Falls from a height	1695	1594	1544	1443	1228	1389	1406	1462	1554	1438
Falls on the same level	2946	3005	2919	2965	2780	2930	2895	2963	2826	2843
Stepping, kneeling or sitting on objects	1026	1089	1150	1314	1330	1058	1019	1160	1385	1563
Hitting Objects	1542	1459	1349	1497	1455	1404	1251	1164	1200	1132
Being hit by a moving object	4091	3948	3793	4060	4010	3962	3948	3686	3721	3820
Sound and Pressure	928	821	766	1147	1178	1439	1765	1748	1692	1682
Muscular stress while lifting	6264	6332	5924	5702	4990	4752	4801	4723	4813	4731
Muscular stress while handling objects	4693	4598	4112	4481	4176	4591	4253	4457	4421	4453
Muscular stress with no objects being handled	1535	1605	1447	1428	1329	1502	1482	1369	1246	1066
Repetitive movement, low muscle loading	2335	2386	2546	2192	2061	1817	1732	1654	1836	1797
Heat, radiation and electricity	243	218	187	236	238	226	241	217	225	228
Chemicals and substances	430	403	319	318	270	293	244	237	227	232
Biological	73	74	78	59	73	63	74	85	100	118
Exposure to mental stress Factors	2587	2730	2640	2464	2448	2388	2419	2823	2963	2820
Vehicle accident	784	717	802	681	720	858	878	890	918	921
Other	973	1162	856	648	703	453	377	427	609	417
All	**32145**	**32141**	**30432**	**30635**	**28989**	**29125**	**28785**	**29065**	**29736**	**29261**

Source: Worksafe Victoria Statistical Summary 2011-12, p 6.

2.2. Risks to the health of flora and fauna

The potential harms to the environment – a term embracing both flora and fauna and the soils and waterways on which they depend – which arise from the use of agricultural chemicals has been a widely understood policy issue of since the 1960s, when a landmark study found adverse effects from Dichloro-Diphenyl-Trichloroethane (DDT) use. Since this time, the adverse effects of the inappropriate use of agricultural chemicals has been widely documented. These adverse effects are of several types:

- wildlife losses can occur due to the careless application of agricultural chemicals;
- loss of fish stocks can occur where inappropriate application leads to significant chemical run-off into rivers;
- groundwater contamination can occur where significant use of agricultural chemicals is made in an area over a period of time and leaching occurs; and
- pesticide use, particularly where prolonged and/or incorrectly applied, can have environmental effects that extend beyond the target species.

Agricultural chemicals are, necessarily, intended to be toxic to the targeted species. While a key objective in the development of agricultural chemicals is to ensure that they are non-toxic to non-target species as far as possible, the problem of unintended poisoning of non-target plant and animal species remains significant, as does that of contamination of soil and waterways. There are also cases of the deliberate use of agricultural chemicals being misused to target animals not approved to be controlled with the chemical.

The adoption and enforcement of progressively more stringent regulatory restrictions on the use of agricultural chemicals in the ensuing decades, together with chemical industry responses in terms of the development and introduction of more targeted products with significantly reduced toxicity to non-target species has substantially reduced the size of this issue of environmental toxicity resulting from the use of agricultural chemicals over time. However, indicators of continuing problems can readily be identified.

Poisoning of native species

The Department of Environment, Land, Water and Planning (DELWP) Poisoning Intelligence Database shows that there were 14 reports of poisoning of native animals during 2015 and 18 in 2016. The most commonly affected species are possums and birds (chiefly magpies, cockatoos and galahs). It should be noted that many of these reports remain unconfirmed, however, it is also likely that the database records only a relatively small proportion of actual poisoning incidents.

At a national level, an important indicator of the continuing harms to animals due to veterinary and agricultural chemicals is provided by the series of adverse experience reports published by the APVMA[14]. The most recent (2014) adverse experience report describes the purpose of this program as follows:

> *The AERP assesses and classifies reports of adverse experiences from exposure to, the use of, or the administration of a veterinary medicine or agricultural chemical product sold in Australia. This is vital for detecting uncommon conditions not evident and therefore not assessed during clinical or field trials for the initial APVMA registration of a product. It is also used for tracking the incidence of known adverse experiences from some products (particularly veterinary medicines)[15].*

As the above indicates, the adverse experiences which are the focus of these reports are, by definition, expected to be relatively rare. Nonetheless, the most recent report indicates that in 2013, APVMA assessed and classified 3733 adverse experience reports relating to veterinary medicines nationally, of which some 80% were animal health related[16]. A far smaller number of adverse experience reports were made in relation to agricultural chemical products, with only 50 such reports being recorded in 2013. Of these, 54 per cent involved effects on crops or animals, 36 per cent involved human health issues, and 10 per cent involved effects on the environment.

An extremely wide range of specific adverse experiences are recorded in these reports, ranging from mild (trembling, rashes), to moderate (vomiting, collapse, respiratory problems) to severe, with the death of one or more animals being noted as the result in a substantial number of cases.

The current regulatory environment attempts to address the risks to the environment arising from the use of agricultural chemicals in several ways. In particular, the Federal regulatory controls on the registration of agricultural and veterinary

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[14] These are entitled ***Report of Adverse Experiences for Veterinary Medicines and Agricultural Pesticides*** and are available here: http://apvma.gov.au/node/10946 .

[15] APVMA (2014). ***Report of Adverse Experiences for Veterinary Medicines and Agricultural Pesticides***, p 1.

[16] 17% of the reports related to lack of efficacy, while the remaining 3% related to human health issues.

chemicals limits the range of chemicals which can be supplied for use, and have progressively led to the removal of some of the most toxic chemicals as safer alternatives have become available. At the same time, the state based regulatory control of use arrangements include licence and permit systems which are based on ensuring that users have undergone adequate training to ensure that their use of these chemicals is competent and responsible.

2.3. Risks to export and domestic trade

Non-compliance with agricultural chemical regulations, including those requiring withholding periods to be observed after application, can lead to situations in which chemical residues are present in agricultural produce (whether plant or animal-based) at levels above those specified in relevant safety standards. Where such residues are detected, significant loss of customer confidence in product quality can result, with potentially significant negative consequences for both domestic and export trade in agricultural products.

Given the economic importance of this issue, as well as its potential impact on human health, the Australian government conducts an annual National Residue Survey and publishes annual reports of the results of these surveys. The survey involves conducting extensive sampling of a wide range of both plant and animal-based agricultural products and testing the samples obtained against the relevant Australian Standards. Table 2.3 sets out the results of the most recent National Residue Survey.

Table 2.3: National Residue Survey Results – 2015/16

Product Type	Total number of samples	Total number of tests conducted	% compliant with Australian standards	Number of non-compliant samples
Animal products (36 types sampled)	9,157	17,700	99.27	129
Plant products (32 types sampled)	7,106	10,300	98.80	124
Total	**16,163**	**28,000**	**99.10**	**253**

Source: Department of Agriculture and Water Resources

Table 2.3 shows that overall there is a high level of compliance with the relevant Australian standards in relation to chemical residues, with 98.8% of tests on plant products and 99.27% of tests on animal product samples being compliant. Nonetheless, a significant number of non-compliant samples continue to be detected, with approximately 253 non-compliant samples detected in the most recent year.

This data is consistent with a generally effective regulatory regime, but one in which continued monitoring and surveillance, as well as efforts to maintain and improve compliance levels remain necessary. This necessity is driven in part by the potentially serious implications for trade (domestic and export) for the agricultural industry and, in particular, the export trade. A recent case study illustrates this point.

Case Study: Herbicide residues in barley exported to Japan

In February 2014, unacceptable levels of residues of the herbicides, *imazapic* and *imazapyr*, were detected in barley sampled as part of a Japanese Ministry of Agriculture, Forestry and Fisheries (MAFF) surveillance program. MAFF Japan responded to the finding by requiring every Australian barley shipment to be analysed for the next five years, thus creating significant costs and logistical problems for the barley export industry. Consultation with industry suggests that a full cohort of 38 analytical tests costs $5,000 per test and represents an industry cost of about $250,000 per year.

Any further incidents of unacceptable residues being detected in the short to medium term could result in long-term loss of access to the Japanese market seriously impacting export revenues and profits. Any such loss of access to the Japanese market could have wider implications, as regulatory authorities in some other export markets typically take their lead from Japan. Loss of market access to other key export markets could be a potentially significant additional cost to industry.

DEDJTR believes that the contaminated barley samples most likely resulted from the off label use[17] of two herbicides (ie *imazapic* and *imazapyr*) as an alternative to using the APVMA approved product containing imazapyr and imazamox[18].

[17] "Off-label" use means use of an AgVet chemical contrary to the instructions provided on the product label – i.e. in a manner other than that authorised by regulation.

As a follow-up to this incident, the Grains Research and Development Council issued a warning to its members as a result of the Japanese actions.

Spray drift

Spray drift occurs when agricultural chemicals (i.e. pesticides or herbicides) are sprayed onto a target (e.g. crop) from either the ground or the air and a proportion of the spray instead "drifts" onto surrounding land. Spray drift is likely to occur when spraying is conducted in inappropriate weather conditions. Spray drift can be of concern in relation to human health, particularly in relation to sensitive populations (e.g. the old, the very young and the immune-compromised). However, it is also a potential source of crop and/or stock contamination and may also pose risks to market access. Table 2.4 summarises the number of spray drift investigations[19] undertaken by DEDJTR since 2009-10.

Table 2.4: DEDJTR Spray drift investigations, 2009-10 to date

Year	No. of Spray drift Investigations
2009-10	29
2010-11	11
2011-12	15
2012-13	13
2013-14	18
2014-15	14
2015-16	21
2016-17 (as @ 9/12/2016)	6
Annual average (to 2015-16)	**17.3**

Source: DEDJTR

Table 2.4 shows that, while there is a degree of year to year variation, with the annual number of investigations varying from 11 to 29 in the period, there is no obvious trend in the number of spray drift investigations undertaken each year. An average of 17.3 investigations were conducted annually.

2.4. Residual risk

The existence, over a long period of time, of a highly developed regulatory regime means that it is not possible to observe the extent of the problems in the above areas that would occur in an unregulated environment. However, it is clear that a significant number of incidents involving the inappropriate use of agricultural chemicals continue to occur despite the existence of this regulatory environment. These incidents constitute indicators of the "residual risk" in this area – i.e. the extent of the problems that continue to be experienced even in a context of the existence of a long-standing regulatory regime which is consistent with international good practice.

The following provides some summary data on these residual risks. However, in many cases, the available data is generic in nature. That is, it does not allow distinctions to be made in terms of the risk (or actuality) of the various specific types of harms discussed in the above sections.

The RIS prepared in 2007 in respect of the current regulations included the following data in relation to the number of chemical incidents in Victoria. It is included here in order to provide historical context for the more recent data reported below.

[18] https://grdc.com.au/Media-Centre/Ground-Cover/GC110/Japan-warns-barley-exporters-about-residues

[19] Spray drift investigations are undertaken by DEDJTR in response to complaints received.

Table 2.5 Chemical incidents in Victoria – 2000 to 2004

Year	Notifications	Investigations	Concluding letters	Court cases	Infringement notices
2000	106	23	16	1	2
2001	126	44	25	0	3
2002	107	36	30	4	4
2003	59	29	11	3	14
2004	70	24	15	3	11
Total	**468**	**156**	**97**	**11**	**34**
Annual Average	**93.6**	**31.2**	**19.4**	**2.2**	**6.8**

Source: DEDJTR

Table 2.5 shows that an average of more than 93 notifications of chemical incidents occurred annually over the five years to 2004, with an average of 31 investigations being undertaken each year. These investigations resulted in 34 infringement notices being issued and 11 chemical incidents resulted in court action being taken.

Among the incidents prompting investigation and enforcement action were off target spraying of chemicals, resulting in crop damage; the use of unregistered chemicals potentially harming the environment or contaminating food; the use of chemical products for prohibited purposes and the unlicensed use of restricted chemical products.

In practice, the majority of these incidents relate to off target spraying of chemicals (i.e. “spray drift”): spray drift accounted for 394 of the 468 notifications recorded in the five years to 2004 and accounted for all of the reported court actions. Approximately one quarter of the total number of spray drift incidents were the result of aerial spraying, while the remaining three quarters were the result of ground-based spraying.

Table 2.6 provides equivalent data in relation to chemical incidents for the eight years to 2015 – 16 i.e. the majority of the period of operation of the current regulations. It shows that there is a significant level of year-to-year variation in activity levels, which makes comparisons across time periods difficult. Overall, however, the level of activity appears to be broadly similar to that reported in the 2007 RIS. For example, the average number of investigations conducted annually over the past eight years is 38.5, compared with 31.2 in the five years to 2004. Of the average of 38.5 investigations conducted annually, the majority related to spray drift (17.3 per annum) and the use of Sodium Fluoroacetate (1080) (14.3 per annum).

Table 2.6: Chemical incident investigations Victoria 2008-09 to 2015-16

Year	Audits/surveys	Investigations	Residue Tracebacks
2008-09	84	7	3
2009-10	310	33	39
2010-11	24	49	93
2011-12	92	18	73
2012-13	33	43	92
2013-14	50	67	102
2014-15	24	33	53
2015-16	93	58	125
Total (8 years)	710	308	580
Annual Average	**88.8**	**38.5**	**72.5**

Source: DEDJTR

Table 2.7. summarises the number of calls to the DEDJTR Customer Service Centre (CSC) in relation to spray drift over the past 10 years. A call to the CSC is the first point of contact with DEDJTR for a member of the public raising a concern about possible spray drift. After discussion, callers are likely to be put into contact with a Chemical Standards Officer to discuss their spray drift issue, which may relate to concerns regarding human health, nuisance, crop damage, residue contamination or environmental harms etc.

Table 2.7: Calls to the CSC regarding spray drift – 10 years to 2015-16

Year	Number of calls relating to spray drift
2006-2007	19
2007-2008	64
2009-2009	42
2009-2010	48
2010-2011	35
2011-2012	47
2012-2013	47
2013-2014	49
2014-2015	41
2015-2016	56
Average	**44.8**

Source: DEDJTR

Table 2.7 shows that, while there has been some year to year variation, as would be expected, the number of calls to the CSC in relation to spray drift has remained approximately constant over time. The total number of calls received over the 10 year period was 448, giving an annual average of 44.8 calls.

The context is one in which the total number of licences on issue, as well as the number of licences in specific categories, has been relatively stable over time, as shown in Table 2.8 below. The total number of licences and permits on issue in July 2016 was 20,395, representing an increase of 2994, or 17.2% on the number on issue 10 years earlier. The table indicates that this modest increase in numbers has been spread across all licence and permit categories. This modest increase in licence numbers is broadly reflected in the modest increase in average investigation numbers noted above.

Table 2.8: Number of licences on issue as at 1 July – 2006 to 2016[20]

Year	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
ACUP	16791	15256	15499	16230	16636	16948	17454	18155	18603	19049	19543
COL	549	570	408	447	514	672	720	759	743	746	768
AAOL	24	25	24	25	27	33	30	29	30	30	32
PCRL	37	36	33	40	35	50	42	43	43	48	52
Total	**17401**	**15887**	**15964**	**16742**	**17212**	**17703**	**18246**	**18986**	**19419**	**19873**	**20395**

Source: DEDJTR

[20] ACUP = Agricultural Chemical User Permit; COL = Commercial Operator Licence; AAOL = Agricultural Aircraft Operator Licence; PCRL = Pilot (Chemical Rating) Licence.

Table 2.9 provides supplementary information, setting out the results of the enforcement activity undertaken as a result of the investigations summarised in Table 2.9. It shows that a total of 72 enforcement actions have been undertaken over the past eight years, or around nine per annum on average.

Slightly more than half of this total (38) involved the sending of warning letters, while infringement notices were the next most common action taken, with 21 issued over eight years. Eleven prosecutions were undertaken during the period. This represents an average of 1.4 prosecutions per annum, although almost half of the total prosecutions were undertaken in 2016. A licence or permit was suspended in only two cases.

Table 2.9: Summary of higher level enforcement actions, 2009 - 2016

Outcome	2009	2010	2011	2012	2013	2014	2015	2016	Total
Suspension of Authority	0	0	1	0	1	0	0	0	2
Prosecution	0	0	3	2	0	1	0	5	11
Infringement Notices	0	4	2	1	5	6	2	1	21
Warning Letter	2	2	4	14	8	3	4	1	38
Total	**2**	**6**	**10**	**17**	**14**	**10**	**6**	**7**	**72**

Source: DEDJTR

Comparison of the number of infringement notices issued in the two periods shows that substantially fewer infringements have been issued in recent years, with an average of 2.6 per year issued since 2009, compared with 6.8 per year between 2000 and 2004. Similarly, average prosecution numbers are down from 2.2 per annum in 2000 – 2004 to 1.4 per annum since 2009.

Given that the number of investigations conducted annually is higher in the most recent period (38.5 per annum since 2009, compared with 31 per annum from 2000 to 2004), these data suggest that compliance levels have increased in recent years – that is, that the proportion of investigations that yield a finding of non-compliance requiring sanctions to be issued has declined significantly. That said, the above caveat as to the relatively low absolute numbers reported and high level of year to year variability in the data is relevant and underlines the need for caution in drawing conclusions from the data.

Overall, DEDJTR believes that, as a result of the consistent application of the regulations over recent decades, there is a relatively high overall level of compliance, which is reflected in these relatively low levels of incident, investigation and enforcement activity, which can be seen to have broadly plateaued in recent years.

2.5. The rationale for regulation

A key element of the rationale for regulatory intervention in agricultural and veterinary chemical use lies in the concept of externalities. That is, regulation is likely to be socially beneficial if it addresses situations in which the costs of one party's actions are imposed on another party.

The importance of this concept is most readily seen in the discussion of risks to export markets contained in the previous section. As noted in the case study, a small number of cases of contamination of animal or plant products by chemical residues can be sufficient to lead to either the exclusion of an industries product from one or more important markets or, at a minimum, the imposition of costly additional testing and verification requirements. Thus, the entire industry sectors can suffer substantial costs as a result of isolated cases of chemical contamination. Such contamination can be the result of poor practices by one or two producers within the affected industry or, in other cases, can be the result of contamination which has its origin outside the industry (e.g. where spray drift contaminates an adjacent crop, or grazing land).

3. OBJECTIVES OF THE PROPOSED REGULATIONS

The objective of the proposed regulations is to minimise the risks associated with the use of agricultural and veterinary chemicals, in order to:

- protect the health of both the general public and chemicals users;
- protect the domestic and export trade in agricultural produce and livestock;
- protect the environment;
- protect the health and welfare of animals; and
- protect against financial loss caused by damage to plants and stock from agricultural spraying

The proposed regulations contribute to the achievement of these objectives by prescribing:

a) the records to be made and kept by users and sellers of certain chemical products;

b) requirements for labels and advice notes accompanying certain veterinary chemical products sold by veterinary practitioners for the treatment of stock;

c) information to be provided in relation to certain agricultural spraying to be carried out on land near schools, hospitals, aged care services or children's services;

d) the equipment to be used when carrying out aerial spraying;

e) certain agricultural chemical products the possession of which is prohibited;.

f) chemical products to be used in accordance with instructions on label or a permit; and

g) other matters authorised by the Agricultural and Veterinary Chemicals (Control of Use) Act 1992.

4. HOW DO THE REGULATIONS ADDRESS THE IDENTIFIED PROBLEMS?

4.1. Overview of the current regulations

The following discussion briefly explains the means by which the specific regulatory controls adopted aim to help to address the problems identified in section 2 and thus contribute to the achievement of the regulatory objectives set out in section 3.

Recording requirements

The key purpose of the recording requirements contained in Regulations 5, 6, 7 and 11 is to facilitate investigations undertaken by the Department, or other regulatory authorities, in response to incidents or notifications. Access to information on what chemicals have been applied, by whom, in what amounts, and in what context can, for example, assist in determining how produce has come to be contaminated and, where necessary, support the application of sanctions, including prosecutions.

Records allow assessment of the nature and extent of exposure to agricultural and veterinary chemicals at either an individual or population level. At an individual level, records will assist medical practitioners to more effectively treat cases of chemical injury. At a population level, records are also important in investigating potential public health risks.

Regulators also require accurate records to enable them to respond effectively to potential harms to animals, crops and the broader environment arising from chemical use. As harms are often not identified until days or sometimes months after application, records are essential in establishing the facts of the chemical use, determining responsibility and informing decisions as to what, if any, remedial actions should be taken.

Labels and advice notes

The labelling requirements contained in the regulations help to ensure that veterinary chemicals are using are appropriately identified and provide sufficient instruction to provide for safe and effective use. By contributing to appropriate use, potential animal welfare problems are minimised and, importantly, residue problems are also avoided.

Aerial spraying equipment

The requirement that pilots conducting aerial spraying must have access to one means of establishing wind direction is intended to contribute to the minimisation of spray drift, since knowledge of wind direction is fundamental to good practice in this regard.

Notification of aerial and mister spraying

The requirement to notify adjoining schools, hospitals and aged care facilities of intended aerial and mister spraying is essentially precautionary in nature, given the various regulatory controls which are in place that seek to minimise the incidence of spray drift. However, the provision of notice to managers of these facilities, which have numbers of people who are likely to be more than usually sensitive to chemical exposures, enables them to choose whether they wish to undertake any additional actions to minimise any risk of chemical exposure resulting from spray drift (e.g. closing windows, recycling air-conditioning). At least 24 hours' notice of intended spraying must be provided and the chemicals to be sprayed must be identified.

Chemicals requiring licence for use

The regulations provide that all agricultural chemical products are the prescribed class of chemical products for the purposes of section 30 of the Act and, consequently, can only be used by licensed persons. This regulation therefore gives effect to a key aspect of the licensing provisions of the Act. By adopting a broad definition of the Act's term "prescribed chemicals" it ensures that the licensing requirements are, similarly, broadly applied. In practical terms, this means that only persons who have undergone training are able to use prescribed chemicals. Thus, restricting the use of prescribed agricultural chemicals to trained persons should contribute to the minimisation of inappropriate use. The risks associated with commercial use are not limited to 'higher risk' chemicals and, as a consequence, it is considered that training requirements should be applied to all users[21]. However, there are exemptions to s.30 which are applied via an Order, rather than in the regulations as there is the scope to exempt certain practices (e.g. use in residential gardens), which cannot be done in the regulations.

The nationally agreed *Single National Framework for The Regulation of Agricultural Chemicals and Veterinary Medicines* provides for the licensing and training requirements for fee-for-service applicators of agricultural chemicals. The proposed licensing model requires all fee-for-service providers to be licensed, and trained at Australian Qualifications Framework level 3 competency as a minimum. This training requirement recognises the higher risk from fee-for-service providers due to the greater extent of their chemical use.

Testing of stock or produce at the owner's expense

The regulations specify that the testing of stock or produce can be conducted at the owner's expense if the owner has consigned contaminated stock for slaughter in the last two years or has been convicted of one of a range of offences relating to agricultural chemicals. The aim of stock/produce testing in this context is to protect human health from the contamination of food for human consumption and protect key product markets by ensuring that products containing unacceptable chemical residues are not sold into these markets. In this context, the purpose of the provision that the testing cost is to be borne by the owner in certain circumstances is to respond appropriately to the fact that the prior actions of the producer have given rise to the need for this testing in the relevant circumstances. This provision provides an additional disincentive for inappropriate chemical use by making those who have been detected using chemicals inappropriately liable for additional financial costs. From an economic perspective, it helps to internalise the costs arising from inappropriate chemical use, which would otherwise be borne by the broader society.

Grounds for refusing a licence or permit

Regulation 16 provides that it is grounds for the Chief Administrator to refuse a licence or permit application that the specified training has not been undertaken. This regulation can be regarded as clarifying in nature, since training requirements are specified via another instrument. However, it persists in ensuring that only qualified persons are able to use agricultural chemicals.

[21] In any event, even if a narrower definition of "prescribed chemicals" were employed, so that it was possible to provide services as an unlicensed commercial operator, using only lower risk chemicals, it is unlikely that this would prove to be a commercially attractive, or viable, proposition.

4.2. Proposed changes to the regulations - general

The following summarises the substantive changes proposed to be made to the current regulations and briefly explains the purpose of each proposed change. The regulation numbers given relate to the draft regulations, except where it is specifically noted, for comparative purposes, that a reference is to “current regulation X”.

4.2.1. Revisions to existing regulations

Proposed Regulation 6: records of use of agricultural chemicals

It is proposed to rationalise the current agricultural chemical record keeping requirements, to align them with agreed nationally consistent standards. The key changes are:

- *Removal of the quality assurance exemption*. While the regulations allow for users of a quality assurance (QA) program to seek exemption from the record-keeping requirements, such exemptions have never been sought in practice by those responsible for any QA program. Further, it is a principle of the national standard that mandatory record keeping standards for all agricultural chemical users will provide a foundation for additional risk management by industry quality assurance and stewardship programs, which may require additional record keeping. Thus, the availability of an exemption is *a priori* inconsistent with this principle. In any event, compliance with a QA program should, by default, result in compliance with the regulations.
- *Specific record keeping requirements for poison bait and outdoor spraying will be removed*. Simplified record keeping elements will instead apply to all methods of application, other than those specifically exempted. The Department considers that this will reduce regulatory burdens while maintaining adequate traceability.
- *Less prescriptive requirements will be adopted in respect of recording the rate of use of chemicals, while multiple sources of the ‘record’ of use will be acceptable*. This change will provide users with greater flexibility as to how they make and keep records and provide greater certainty of compliance for users.

The changes are expected to reduce the cost of complying with the record keeping requirements, while maintaining effective regulatory standards.

Proposed Regulation 7: records of use of veterinary chemicals

A minor change to this regulation is proposed to include hormonal growth promotants (HGPs) amongst the chemicals which must be recorded, with the animal to which they are administered also to be recorded. Inclusion of HGPs within the scope of regulation 7 will be balanced by the removal of the separate record-keeping requirements in relation to HGPs (current regulation 11).

The net result of this change will be a rationalisation of the regulations, with consistent requirements adopted across the relevant range of chemicals.

Proposed Regulation 10: veterinary chemical labelling and advice notes

A minor addition to the current requirements is proposed, with the batch number and expiry date (if known) of the product to be included on the label and/or advice note. This will contribute to maintaining product traceability to the end user, by providing more specific identifying information on the product label.

Former Regulation 11: Records of use of hormonal growth promotants

The National HGP Control and Monitoring System provides assurance to international markets by enabling Australian authorities to account for the importation, supply and use of HGPs. This includes a Commonwealth regulations that require HGP suppliers to keep accurate records of supply to provide traceability. The current Victorian requirements associated with users recording the supply and possession of HGPs are duplicative and should not be continued.

Given the trade risks associated with HGP use, it is appropriate that a regulatory requirement for general records of HGP use is maintained so as to provide the ability to monitor use, particularly where it may occur outside of an industry quality assurance program. HGPs will be included in the proposed regulation 7 with other veterinary chemical where records of use must be made.

Proposed Regulation 12: notification of agricultural spraying near services

The revised regulation is intended to improve the ability to sanction non-compliance by an occupier of land who fails to provide notification to the manager of the sensitive community service by making it clear that the responsibility in this area lies solely with the occupier. This includes proposed changes to the wording of the regulation to clarify requirements applicable to land occupiers, employees and contractors.

Specifically, it is proposed to remove the current requirement that employees and contractors not start spraying until they receive notification from the land occupier whether or not there is a sensitive service within 200m. This will help to make it clear to land-occupiers that they bear the primary responsibility for ensuring that notification is carried out.

Proposed Regulation 16: aerial spraying equipment

It is proposed to amend current regulation 14 to provide greater flexibility in managing the risk of spray drift. Specifically, as an alternative to the current equipment requirements, a pilot will be able to undertake aerial spraying if they are in continuous radio communication before and during the spraying with a ground based person near the point of spraying who uses equipment to measure the wind speed and direction.

Proposed Regulation 17: testing of stock and agricultural produce at the expense of the owner

A number of changes to this regulation are proposed to improve the ability of Authorised Officers to manage the risks to trade associated with contaminated produce.

Current regulation 15 enables testing at the owner's expense if the owner has sold or consigned for slaughter contaminated stock or sold or consigned for sale contaminated agricultural produce within the last two years or if the owner has been convicted of an offence under certain sections of the Act or of the *Drugs, Poisons and Controlled Substances Act 1981*(the DPCS Act). Proposed regulation 17 changes these provisions in two respects:

- In relation to the sale or consignment of contaminated stock, reasonable suspicion that the owner had done so would be sufficient to trigger this provision; and
- In relation to offences under the prescribed provisions of the two Acts, a finding of guilt would be sufficient to trigger the provisions, even if a conviction was not recorded.

Finding of guilt

The proposed change in respect of offences under the prescribed sections of the Act (and the DPCS Act) will align this provision with the powers currently provided to Authorised Officers to issue contaminated stock notices or contaminated produce notices under the Act. Moreover, it is considered that the appropriate test, in determining whether the owner should pay for testing (rather than the taxpayer) is that of whether the offence is proven, rather than whether the judge or magistrate chose to record a conviction in the specific case. This proposed change reflects the fact that DEDJTR believes that, in general, it is now common for a finding of guilt to be made by a court without a conviction being recorded in relation to many types of offences, such as this one[22]. That said, it is extremely rare for this provision (i.e. testing required to be undertaken at the owner's expense due to a conviction for selling contaminated stock or produce being recorded) to be used in practice. Hence, the adoption of this change is expected to have very little practical impact.

Reasonable suspicion

The proposed change to enable testing at the owner's expense where there is "reasonable suspicion" that a person has sold contaminated stock or produce necessarily entails a potential infringement of individual rights, in circumstances where such "reasonable suspicion" turns out to be unjustified. However, this change is considered to be necessary and justified because there may be circumstances in which a timely response to manage the potential public health and trade risk posed by contaminated produce requires the acceptance of reasonable suspicion.

For example if residue monitoring finds that produce or stock are contaminated, a traceback investigation may determine that there is comparable produce in production or storage that is also likely to be contaminated. However, there may be a small amount of uncertainty around the traceability of the original contaminated sample. This may be addressed through the gathering of additional evidence, but the time to undertake these additional investigative activities may prevent the timely regulatory response to the risk posed by the contaminated produce. In such cases, "reasonable suspicion" on the part of Authorised Officers is likely to be very well-founded and clearly suggests that the "owner's cost" provisions should be triggered.

4.2.2. New regulations proposed to be adopted

Proposed Regulation 13: Prescribed chemical products to be used in accordance with instructions on the label, or a permit

A requirement that 'restricted use' agricultural chemicals, such as Schedule 7 Poisons, ester formulations of 2,4-D, 2,4-DB, MCPA and triclopyr, only be used "on label" – i.e. in accordance with the manufacturer's directions – is currently established by a Ministerial Order made under the Act. It is proposed to transfer these requirements to the regulations.

[22] Specific data on the number of convictions and findings of guilt in respect of these offences are not currently available.

The APVMA may already issue permits to allow the use of unregistered products in Victoria. However, unlike other states and territories Victoria does not currently allow the APVMA to issue permits for off label use. APVMA permit holders must also obtain a Victorian permit to allow the off label use of these 'restricted use' chemicals.

The proposed regulations constitute an "eligible law" under the AgVet Code of Victoria[23] which thereby enables the APVMA to issue permits for off label use of these 'restricted use' chemicals. This should streamline approvals arrangements, effectively creating a single process for approvals by allowing recognition of a national process in Victoria. It thus helps to avoid possible regulatory duplication.

This proposal will remove the duplication in permit processes as applicants will only need apply to the APVMA for a permit. In addition, the APVMA assess and issue permit for all other states and territories. They therefore have the capacity and capability to undertake permit assessments in a more efficient and effective manner. Further, the APVMA have a modulated fee structure to better cater for the variety in complexity of the application's assessment, which would generally allow for lower fees compared to Victoria.

Further this will provide industry with greater certainty in obtaining access to approved chemical uses.

Proposed Regulation 14: Offence to possess certain unregistered agricultural chemicals

A new regulation is proposed, prohibiting possession of seven specified unregistered agricultural chemicals[24]. Exemptions will apply where a permit is issued to authorise use or possession and where the chemical is being stored at a facility for its disposal or in transit to a facility for its disposal.

This regulation is intended to encourage the disposal of specified unregistered agricultural chemicals that are likely to pose a risk, particularly intentional misuse as a vertebrate poison.

Remake current Orders in Council

Moving current controls on the off label use of 'restricted use' chemicals to the regulations, necessitates remaking two Orders in Council. These are the G50 13 December "*Order Regulating the Use of Agricultural Chemical Products by Authorised Personnel*" and the G51 20 December 2007 "*Order Regulating the Use of Perishable Pest Animal Baits Containing Sodium Fluoro-acetate* (1080). The revised Order authorising 1080 will effectively remove the prohibition on the use of grain-based perishable pest animal baits containing 1080 for the control of feral pigs subject to permit or label directions. This change will be introduced to address concerns regarding the limited feral pig bait products available for use in managing biosecurity risks such as an outbreak of foot and mouth disease, where rapid and effective control of feral pigs is necessary to ensure that feral pig populations do not harbour the disease. The change will provide an authorisation pathway via a permit or expanded on label use.

4.3. Consideration of feasible alternatives

The proposed regulations, incorporating the range of specific changes to the existing regulations identified above, have been developed by DEDJTR as part of a policy development process that has included significant consultation with a range of stakeholders. As part of this process, a range of feasible alternatives were identified and considered for inclusion in the proposed regulations. The key alternatives considered were:

- adopting a performance-based regulation in relation to spray drift management;
- removing the notification requirement in respect of spraying near services;
- adopting a compulsory reporting requirement for laboratories that detect contaminated produce; and
- adopting a general prohibition on the possession of unregistered AgVet chemicals.

Sections 5 and 6, below, discuss the expected benefits and costs of the proposed regulations, with the benefits and costs being measured against a base case in which the sunsetting regulations are not remade. Section 7 goes on to describe the key alternatives considered (as enumerated above), to assess the expected benefits and costs of each, and to discuss the reasons for rejecting each of these alternatives. In particular cases, where there is significant uncertainty as to the relative impacts of key parts of the regulations and the alternatives, specific stakeholder questions are included in the text. The department particularly seeks stakeholder response in relation to these issues and will take these responses into account before finalising its position in relation to the potential inclusion of the feasible alternatives in the new regulations.

[23] This is a Code adopted nationally under the Agricultural and Veterinary Chemicals Code Act 1994 and incorporated by reference into Victorian legislation. See: Agricultural and Veterinary Chemicals (Victoria) Act 1994.

[24] These are fenthion, fenthion-ethyl, strychnine, arsenic (other than arsenic used to treat wood), parathion, parathion-ethyl and parathion-methyl.

5. EXPECTED BENEFITS OF THE PROPOSED REGULATIONS

5.1. Overview – reduction of the identified risks

As discussed in section 2, the current regulations constitute a relatively small element in a much larger regulatory structure. This larger regulatory structure, taken as a whole, provides substantial benefits for the protection of human and animal health, the environment and access to product markets. However, there are inevitably certain difficulties in identifying benefits that are directly attributable to the regulations.

Available evidence, including that discussed above in section 2, suggests that the harms associated with the use of agricultural and veterinary chemicals in Victoria, and Australia generally, are small and that they appear to be declining over time. This suggests that the current regulatory system, taken as a whole, is largely effective in achieving the objectives identified in section 3. Within this broader context, the following discusses the expected benefits associated with the specific provisions of the current and proposed regulation.

5.2. Benefits related to the specific content of the regulations

The key specific provisions of the regulations are as follows:

- establishing a requirement for all commercial users of chemicals to have a Commercial Operator Licence (COL) (thus giving effect to Section 30(1) of the Act);
- requiring aerial spraying to be undertaken only where certain equipment is available;
- requiring notification of aerial or mister spraying to nearby schools, hospitals, children's and aged care centres;
- establishing a range of requirements for the labelling of agricultural and veterinary chemicals; and
- establishing a range of record keeping requirements.
- prohibiting the possession of specified unregistered products

The following discusses the expected benefits associated with each of these specific aspects of the regulations in turn.

5.2.1. Requirement for all commercial users of chemicals to be licensed

Section 30(1)(b) of the Act states that a person must not carry on business using a prescribed chemical product for a fee or reward unless they are licensed. The regulations give effect to this provision by specifying that the prescribed class of chemical product used includes all agricultural chemical products. This has the effect of requiring all commercial users (i.e. those using agricultural chemicals to supply services to other parties) to be licensed.

The primary benefits sought via licensing commercial operators are fourfold:

- It enables qualification requirements to be established as a condition of licensing, thus ensuring the competence of licensed persons. In the current context, this focuses specifically on the completion of adequate training in the safe use of relevant chemicals;
- It facilitates investigations and enforcement activity by DEDJTR in circumstances in which actual or potential adverse impacts due to the inappropriate use of agricultural chemicals have been identified. This is supported by DEDJTR maintaining an up-to-date database of all operators who are authorised to use agricultural chemicals in a commercial context;
- It enables unsatisfactory operators to be removed from the industry via the exercise of the sanction of cancellation of the licence; and
- It establishes a licence/permit system which provides a mechanism by which the costs of regulating the industry can be recovered from industry participants. That is, even without an explicit licensing scheme, significant regulatory monitoring and enforcement costs are incurred by government. The adoption of a licensing requirement provides for the recovery of these costs, while imposing only modest additional costs. This helps achieve economic efficiency and equity objectives, consistent with the Department of Treasury and Finance Cost Recovery Guidelines.

The high level of toxicity of many agricultural chemicals (as discussed in section 2) provides one rationale for extending the scope of the COL broadly, as the current regulations have done and the proposed regulations will continue to do. The highly toxic nature of a wide range of agricultural products implies that the potential for harms due to the incompetent or inappropriate use of these products is substantial. The size of this sector (i.e. commercial providers of services using

agricultural chemicals) is also substantial, as indicated by the fact that there are approximately 782 licensees in this category at present. This further underlines the potential for harm to arise from the use of these chemicals by poorly-trained operators. Moreover, as a matter of practicality, a commercial operator will typically be called on to use a range of different chemicals in different circumstances. Thus, even were it possible to carry on a business using a subset of less toxic chemicals without a licence, commercial reality suggests that few commercial operators would choose to avoid the licensing requirement by restricting their scope of operations in this way.

In addition, factors other than the toxicity of these chemicals contribute to the risks posed by incompetent operators. For example, problems of damage to crops or animals due to inappropriate use, or of potential loss of access to markets due to residues being detected following problems of inadequate recording of the details of use can give rise to substantial harms.

Importantly, many users of the services of licensed commercial operators would be poorly placed to make judgements for themselves as to the competence of a commercial operator's ability to carry out the required work. This may reflect the low level of knowledge of the relevant chemicals among many of those who use the services of commercial operators, as well as the fact that they may use their services only infrequently. In addition, some of the risks associated with the use of these chemicals may not become apparent until long after use has occurred.

These factors imply that normal commercial incentives would be insufficient to ensure that incompetent operators are excluded from the market. Further, no industry standards or accreditations apply to the majority of commercial operators to provide industry self-regulation.

Given these factors, the Department considers that there is a strong, in principle case that requiring licensing for the commercial use of the broad range of agricultural chemicals should provide significant benefits to society.

5.2.2. Requiring aerial spraying to be undertaken in specified circumstances

Current regulation 14 specifies that aerial spraying can only be undertaken where certain equipment is available. The proposed regulations will broadly maintain these requirements, albeit that some additional flexibility will be added.

The expected benefit of this regulation is that it ensures that those undertaking aerial spraying have information available to them in relation to wind speed and direction and, as a result, are able to ensure that spray drift is prevented or minimised. That is, these provisions are aimed at preventing accidental exposure to agricultural chemicals for people, animals and/or crops.

As shown in section 2, the number of spray drift incidents investigated by the DEDJTR in recent years has been consistently low, averaging slightly more than 17 incidents per annum. A strong industry association, the Aerial Application Association of Australia (AAAA) exists, which covers a large proportion of those providing aerial spraying services and which also undertakes significant efforts to ensure a high standard of performance is achieved. For example the AAAA publishes a detailed Pilots and Operators Manual which aims to provide the guidance necessary to prevent spray drift[25]. This suggests that a relatively high standard of performance might be achieved in the absence of specific regulatory requirements – i.e. that most operators would be likely to adopt appropriate practices for a mixture of commercial and professional reasons.

However, the adoption of specific regulatory requirements enables enforcement to be undertaken where actual performance does fall short of appropriate standards. Moreover, the Department considers that the regulations enhance public confidence on an issue which has historically been of significant concern from time to time and remains sensitive[26]. In addition, consultation with the AAAA indicates that they believe that the specific regulatory requirements go no further than good commercial practice would dictate and as a result, they do not believe that the regulations impose a significant additional cost. That is, additional costs would only be imposed on a minority of operators whose operations might not otherwise met widely accepted professional standards.

5.2.3. Requiring notification of spraying near services

The regulatory requirement that schools, hospitals, aged care and child care centres be notified prior to spraying being undertaken by aircraft or mister is also intended to yield benefits that are primarily concerned with the maintenance of public confidence. As discussed above, incidents of spray drift resulting from aerial spraying are rare, with only a handful being investigated annually. Thus, the actual risks to sensitive populations associated with this activity are, in reality, very

[25] See: http://www.aerialag.com.au/ResourceCenter/Programs/Spraysafe.aspx

[26] See, for example: https://pesticides.australianmap.net/1981-july-brightwandiligong-concerns-over-pine-plantation-aerial-spraying-pesticide-245-t/

small. However, notification ensures that managers of these facilities are aware of aerial spraying about to be conducted and the identity of the specific product to be sprayed. The provision of the trade name of the agricultural chemical allows the manager of the site to access safety data regarding that chemical. This information can assist the manager in determining what, if any, actions are required to care for the site's occupants. This is likely to be as simple as ensuring that windows are closed and/or air-conditioners are set to recycling during and immediately after the spraying.

5.2.4. Labelling requirements

Labelling requirements are intended to ensure that agricultural and veterinary chemicals can be reliably identified. Labelling these chemicals is fundamental to ensuring that they are appropriately used, therefore minimising the risk of inadvertent application of the wrong chemicals for a particular purpose. Correct identification of these chemicals is also important in the context of storage and disposal, helping to ensure that chemicals are appropriately stored and, as required, disposed of in a safe fashion.

5.2.5. Record-keeping

Records allows the demonstration of compliance during audits or investigations where inappropriate use of AgVet chemicals is suspected. Records can also provide vital information in the treatment of chemical incidents including exposure by workers or bystanders. As information may be required days or months after the chemical use has occurred. Records are therefore essential to accurately determine the circumstances of chemical use and must be provided to Authorised Officers when requested.

In addition to the minimum requirement in the regulations, additional records may be kept by individuals and businesses for their own business needs, risk management or to meet market requirements.

5.2.6. Prohibition of possession of certain unregistered agricultural chemicals

AgVet chemicals must be registered by the APVMA in order to be authorised for use. There is constant change in the set of registered chemicals, with new chemicals being brought to market and approved for use and older chemicals having their registration withdrawn, particularly where less dangerous alternatives become available or new concerns as to their toxicity and/or potential for misuse arise. This latter dynamic means that users of AgVet chemicals will often have "legacy" stocks of unregistered chemicals.

The central expected benefit of the introduction of this additional element of the regulations is that it will reduce the likelihood of existing stocks of dangerous, unregistered chemicals being used by licence-holders or others. Such use can potentially be inadvertent, and result from confusion as to the identity of the chemical in question (e.g. due to deteriorated labels). It can also be deliberate, in circumstances in which a user does not hold stocks of an equivalent, currently registered chemical and uses a deregistered chemical rather than undertaking the additional expense of purchasing a new pesticide or herbicide.

In addition, benefits may arise due to the prevention of spillages of these chemicals, which could occur due to factors including failure of the containers in which they are held, or poor handling practices. That is, if the possession of the most dangerous unregistered chemicals is prohibited, it is anticipated that legacy stocks will be surrendered for destruction, thus reducing these risks.

The scope of this prohibition on possession is limited to a range of chemicals that have been identified as particularly dangerous. As only relatively limited stocks of these chemicals are likely to be held currently, it is not anticipated that the overall benefits of this regulatory change will be particularly large. However, given the harms that can occur in specific cases of misuse, this intervention is likely to achieve worthwhile benefits in practice.

Moreover, at a philosophical level, good practice in relation to the husbandry of dangerous goods would suggest the appropriateness of adopting a program to identify and destroy dangerous goods that are no longer authorised to be held and, therefore, have no legitimate uses.

5.2.7. Provision for stock or produce to be tested at the owner's expense

The benefit of proposed Regulation 17 is twofold. Firstly, it provides an incentive to stock-owners and producers to comply with the regulatory requirements in relation to the use of AgVet chemicals, including the observation of withholding periods, as failure to do so gives rise to the potential for them to incur significant additional testing costs. Second, it ensures that, where such testing is required, its cost is not borne by the taxpayer. Thus, it internalises the costs of non-compliance with the regulatory requirements.

It should be noted, however, that the benefits (and costs) associated with this regulation are small. A total of seven *Testing of Agricultural Produce Notices* were issued between 2008 and 2016. Thus, the average number of these notices issued is around one per year. While there is a degree of uncertainty, DEDJTR expects that, under the new provision, the average of number of notices issued could increase to as many as two per year.

Conversely, however, no *Testing of Stock Notices* have been issued in since 2012. Thus, it is quite possible that this change will have little or no practical impact in the near future.

6. EXPECTED COSTS OF THE PROPOSED REGULATIONS

Section 1.2, above, describes the key elements of the current regulations. Based on this description the following substantive costs can be identified as being imposed by the proposed regulations:

- the ***record-keeping costs*** imposed in respect of the use of agricultural and veterinary chemicals and hormonal growth promotions (proposed regulations 6, 7 and 8);
- the ***labelling costs*** imposed via regulations 9, 10 and 11;
- the ***costs of notifying spraying near services***, imposed by regulation 12;
- the ***licensing costs*** imposed via regulation 15;
- the ***aerial spraying costs*** imposed via regulation 16, which establishes various means of minimising the risk of spray drift; and
- the ***costs of having stock and produce tested***, imposed by regulation 17.
- New costs associated with **disposal of specified unregistered products**, imposed by regulation 17.

The nature and extent of each of these costs is discussed in turn below.

6.1. Record-keeping costs

Agricultural chemicals

Proposed regulation 6 requires the recording of the use of agricultural chemicals and affects holders of ACUPs and Commercial Operator's Licences. There are approximately 20,503 and 782 licence/permit-holders in these categories at present, making a total of 21,285 affected parties.

The costs to this group are estimated following the methodology adopted in the 2007 RIS. This assumes, based on stakeholder consultation, that each of the affected licence/permit-holder would record an average of 10 uses of agricultural chemicals per annum and that each use would take five minutes to record in the required format. On this basis, there are:

21,285 x 10 = 212,850 recordings per annum

As each recording takes 5 minutes, or 1/12th of an hour to record, the number of hours required to complete these recording obligations is:

212,850/12 = 17,737.5 hours per annum.

An hourly wage rate of $22.14 has been used, based on the current pastoral award[27], with a 20% labour oncost added[28] to yield an hourly cost of $26.57. Using this labour cost, the annual cost of record-keeping in respect of agricultural chemicals is:

$26.57 x 17,737.5 = $471,285.

In line with the 2007 RIS, it is assumed that 50% of this recording would be undertaken in the absence of the regulatory requirement as a result of commercial imperatives. Thus, the net regulatory cost is estimated at $235,642.50 per annum.

Impact of proposed changes to record-keeping requirements

[27] Using the highest level (Level 8) farmhand rate, which apply to Certificate 3 qualified workers working with limited supervision.
[28] This reflects a narrow view of on-costs, consistent with the "avoidable cost" concept. That is, these activities constitute only a very small part of the functions of the staff involved, making the adoption of a fully distributed costs approach inappropriate.

As noted in Section 4.2, three specific changes to the current record-keeping requirements are proposed to be made in order to align these requirements with agreed national standards, with the overall impact of these changes expected to be a slight reduction in the cost of compliance with this element of the regulations. The expected impacts of the specific changes proposed are:

- *Removal of the quality assurance exemption*. As noted in section 4.2, the keeping of adequate records is a key requirement of all QA programs in this area. Thus, the removal of the current exemption is not expected to increase costs for users of these programs. That is, the records that QA program participants would keep for these purposes are expected to be adequate to achieve compliance with the regulations, so that no additional burden will be imposed. The proposed reduction in the degree of prescription in relation to some areas of the record-keeping requirements supports this conclusion.
- *Removal of specific record keeping requirements for poison bait and outdoor spraying*. Simplified record keeping elements are proposed to be applied to all methods of application, while the specific requirements in relation to baits and outdoor spraying are to be removed. These changes will necessarily reduce regulatory burdens.
- *Less prescriptive requirements in respect of recording the rate of use of chemicals, with multiple sources of the 'record' of use to be acceptable*. By providing users with greater flexibility as to how they make and keep records, this change is also expected to reduce record-keeping costs to some extent. For example, users may record of the amount of chemical applied to a paddock in a written spray diary, but information on the size of the paddock may be recorded in a farm plan. Together, they may be used to calculate the rate of application.

Thus, one proposed change in this area is expected to have little or no impact on compliance costs, while the remaining two are expected to be cost-reducing. DEDJTR anticipates that the extent of these cost reductions will be modest, in relative terms – that is, as a proportion of the current cost of compliance. However, given the limited information available as to current compliance costs, no quantitative estimate of this reduction can be made.

Veterinary chemicals

Proposed regulation 7 requires the recording of the use of veterinary chemicals.

According to Farm Facts 2012 (National Farmers' Federation), there were 120,112 farms[29] in Australia in 2012, of which 24.7%, or 29,668 were located in Victoria. Many of these farms will be engaged wholly or largely in crop production and will therefore make little or no use of veterinary chemicals. However, the Farm Facts publication notes that the three major product types for Victorian farms are milk, cattle and sheep. It is therefore assumed that 50% of the total number of farms identified above will make use of agricultural chemicals. This gives a total of 14,834 farms.

Consultation conducted in the context of the 2007 RIS yielded a "conservative" estimate that veterinary chemicals would be used five times per year on average by the affected population. DEDJTR believes that there has been no substantial change in the overall intensity of use of AgVet chemicals since this time, hence this estimate is believed to remain appropriate.

This implies a total of (14,834 x 5) = 74,170 recordings of the use of veterinary chemicals would be required.

As above, it is assumed that recording takes five minutes on average to complete and that the average labour cost is equal to $26.57 per hour. On this basis, the total cost of recording the use of veterinary chemicals is estimated at:

74,170/12 x $26.57 = $164,225 per annum.

It is assumed that 50% of users would choose to keep these records in the absence of a regulatory requirement, as a result of commercial decisions (e.g. to ensure that withholding periods were observed). Thus, the attributable cost of this regulation is estimated to be half of the above total, or $82,112.50 per annum.

Hormonal growth promotants

The current regulation 11 requires that the administration of hormonal growth promotants (HGP) be recorded. As noted above, this requirement is to be, in effect, integrated with the general requirement to record the use of veterinary chemicals established under current regulation 6. However, while the regulatory requirement is to be streamlined in this way, the scope of the recording requirement remains essentially unchanged. Thus, the use of HGP constitutes an additional recording requirement to that estimated above in relation to veterinary chemicals generally.

According to APVMA, a total of 856,116 doses of HGP were supplied to Victorian users in the year to 30 June 2016, with a total of 170 end users being supplied. This represented more than a fourfold increase on the 185,000 doses supplied in

[29] Farms whose primary business was agricultural production – excludes some "hobby farms" where the major activity is not agricultural production.

2006[30]. Using the 2007 RIS' estimate that an average of 25 head of stock were treated per dosing session, this implies that HGP would have been used on around 34,225 occasions[31].

Using the same assumptions as those employed above in relation to regulation 6, the cost of complying with this requirement is thus:

34,225/12 x $26.57 = $75,780 per annum

This gross cost is also discounted by 50%. This reflects the likelihood that, in the absence of a regulatory requirement, users would typically wish to keep these records for commercial purposes. Such purposes could include ensuring that dosing does not occur too frequently and ensuring that any withholding requirements are met.

Thus, the incremental cost of the regulation is estimated at $37,890 per annum.

Sale or use of veterinary chemicals

Proposed regulation 8 requires veterinary practitioners to record the sale or use of veterinary chemicals for the treatment of stock animals. As it applies specifically to stock animals, this regulation essentially applies to vets practising in regional and rural areas who treat stock as part of their practice. Consultation with the Australian Veterinary Association (AVA) indicates that the dispensing of veterinary medicines would be undertaken during most consultations, with an average of 8 – 10 instances of sale or use per day per vet being estimated.

There are currently approximately 3000 registered veterinary practitioners in Victoria, with around one third of this number believed to be operating in regional and rural areas and thus subject to these requirements which relate to stock animals. Thus, around 1000 veterinary practitioners are believed to be affected by this regulation.

Given this, the total number of instances of recording of the sale or use of veterinary medicines required to be undertaken can be calculated as:

1000 vets x 9 instances per day x 220 working days per annum.

This yields a total of 1,980,000 records of the sale or use of a veterinary medicine per annum.

Consultation with the AVA indicated that separate records are not typically kept for the purposes of compliance with these regulations. Rather, the required details are recorded within the general records kept by the vet. It should be noted that the Veterinary Practitioners' Registration Board enforces requirements that practitioners maintain accurate clinical records at all times. Hence, the recording of the dispensing of veterinary medicines occurs within this context. This being the case, records of the dispensing of veterinary medicines would typically need to be made as part of this professional obligation and the regulatory requirement would arguably place no further burden on practitioners. However, following consultation with the AVA, a conservative estimate has been made that that the recording of the required details would require an additional two minutes to complete, on average.

The number of hours required to comply with the recording requirements is thus:

(1,980,000 x (2/60)) = 66,000

Consultation with the AVA indicated that an average charge rate for a regional or rural vet would be in the vicinity of $120 per hour. Hence, the gross cost of compliance with the recording requirements is estimated at:

66,000 x $120 = $7,920,000 per annum.

However, as noted above, the legislated professional obligations attaching to veterinary practice include specific requirements to keep accurate clinical records, including records of treatments provided. Given this, the AVA believes that, in the substantial majority of cases, vets would record the information required, even in the absence of the specific requirements of the current regulations. Thus, this gross cost must be substantially discounted in respect of these "business as usual" costs, in order to obtain a realistic estimate of the incremental cost of the regulatory requirement. DEDJTR believes that a discount of 90% should be applied to reflect the fact that a similar legislative obligation already exists under the *Veterinary Practice Act 1997*, together with the fact that adequate record-keeping is also an essential practical requirement in running a veterinary practice.

[30] Source: 2007 RIS.

[31] Note that the significant increase in the number of doses supplied since 2006 suggests that that a larger average number of stock may currently be dosed per event than this earlier estimate would suggest. To the extent that this is the case, this will reduce the costs involved below the level estimated here. Hence, the adoption of this assumption from the 2007 RIS imposes a degree of conservative bias on the costings.

On this basis, the incremental costs of the regulations are estimated at:

$7,920,000 x 10% = $792,000 per annum.

Total record-keeping costs

In sum, the net regulatory costs associated with the various record-keeping requirements identified above are:

- $235,642.50 per annum in respect of agricultural chemicals;
- $82,112.50 per annum in respect of veterinary chemicals;
- $792,000 per annum in respect of the sale or use of veterinary chemicals by veterinary practitioners; and
- $37,890 per annum on respect of the use of hormonal growth promotants.

These costs sum to $1,147,645 per annum.

Stakeholder questions: *Do you believe the estimates of the amount of recording activity undertaken for agricultural and veterinary chemical use and the time required to complete it are broadly accurate? If not, what alternative estimates do you believe would be more appropriate? Do you believe that a significant proportion of the required recording activity would be undertaken for reasons other than regulatory compliance? If not, why not?*

6.2. Labelling costs

The costs incurred by veterinary practitioners in complying with the labelling requirements have also been calculated on the basis of estimates provided by the AVA. Based on the advice received from AVA, it is estimated that vets would need to create labels around 8 – 10 times per day on average and that around 2.5 minutes would be required to create a label. The number of labels created annual can thus be estimated as:

9 labels/day x 220 working days x 1000 vets = 1,980,000

The number of hours required to complete this requirement is equal to:

1,980,000 labels x (2.5/60) hours = 82,500 hours

At $120 per hour, as estimated above, this implies a gross annual cost of $9,900,000.

However, given the requirements of the *Veterinary Practice Act 1997* and their broader professional obligations, it is assumed that 90% of vets would provide the required information on labels in the absence of a specific regulatory requirement under the proposed regulations.

Consequently, the incremental costs of this regulatory requirement, as formulated in the current regulations, are estimated at 10% of the above total, or $990,000 million per annum. The proposed addition of a requirement to include the batch number and expiry data on the label is not expected to materially increase this cost.

6.3. Costs of notifying spraying near services

The 2007 RIS, prepared in advance of the introduction of the regulatory requirement to notify aerial spraying or spraying by mister, assumed that only around 50 such notifications would be required annually and that each notification requirement could be completed within 10 minutes – typically through making a phone call or sending a brief letter or email.

This reflects the fact that land use practices mean that spraying by these means rarely occurs in contexts in which such services (i.e. schools, aged care centres, etc.) are located nearby. For the most part, aerial spraying will be conducted in a context of broad acre agriculture, where it confers significant scale economies. Services such as schools and aged care centres are rarely located within close proximity (i.e. less than 200 metres) from such large-scale agricultural land.

Consultation indicates that most of the localised demand for notification of agricultural spraying near services arises in the Goulburn Valley, where there are a number of schools located near orchards that apply chemicals using misters. Authorised Officers report that school Principals value the regulatory requirement as it empowered them to better communicate with their neighbours to ensure the effective management potential spray drift issues. Given the inputs received from Authorised Officers, DEDJTR considers that an average of 200 notifications of spraying is likely to constitute a more reasonable estimate of the practical impact of this notification requirement. That said, it is acknowledged that this estimate remains subject to significant uncertainty.

At 10 minutes per notification, this is equal to 33.3 hours of labour time to complete the notification requirements annually. It is assumed that these notifications are undertaken by the land-holder personally. Using an hourly cost based on average earnings, of $69.82[32], the total cost of the notification requirement is equal to:

33.3 x $69.82 = $2325 per annum.

However, two additional potential costs associated with notification were identified in consultation with the Aerial Application Association of Australia (AAAA). First, the association indicated a view that the notification requirement can give rise to practical difficulties, as it is sometimes necessary to make a rapid decision to undertake spraying at a particular time in order to take advantage of what can be a brief period of suitable weather. It was argued that, in such circumstances, the need to comply with the notification requirement can give rise to a risk that opportunities to spray will be lost.

Second, the association argued that the notification requirement could lead to a "perverse outcome" whereby those notified regularly assume that all pesticide applications have the same level of risk attached to them, may become complacent regarding these risks and, as a consequence, be less likely to undertake risk mitigation actions. DEDJTR does not believe that this argument is sustainable as it is clear that, in the absence of a notification requirement, these groups would clearly have little or no opportunity to take any risk mitigation actions. It is difficult to argue that notification could reduce the extent of such activity.

6.4. Licensing costs

Schedule 1 to the Act deals with permits, certificates and licences (collectively referred to as "authorities"). Section 3 of Schedule 1 states that the chief administrator may grant, or refuse to grant, an authority. It also states that a refusal to grant an authority may be based on any "prescribed ground". The proposed regulation 18 states that:

> *"For the purposes of clause 3(4)(b) of Schedule 1 to the Act, the prescribed ground is that the chief administrator is not satisfied that the applicant for the authority has relevant training to the satisfaction of the chief administrator.."*

Given this, it is arguable that the cost of completing the approved training courses is attributable to the regulations. Table 6.1 sets out the approved training requirements for the two most common types of licence/permit – i.e., the ACUP and the COL. It shows that different training requirements are specified for different subcategories of licence/permit and includes DEDJTR estimates of the average number of contact hours required to complete the training and the cost of the training (i.e. the fee payable to the training provider).

Table 6.1 also includes data on the number of licences/permits of each category issued annually and extrapolates the time, cost and quantity figures to obtain estimates of the total annual cash and time costs of completing the required training.

[32] Based on ABS Cat. 6302.0: Average adult full-time ordinary time weekly earnings for May 2016 of $1,516, divided by 38 hours, equals $39.89/hour. Adding 75% for oncosts and overheads gives a total hourly labour cost of $39.89 x 1.75 = $69.82. The AWE figure has been used in the absence of a reference wage rate for the affected land-holders.

Table 6.1: Summary of training requirements for licensing/permitting

Licence/Permit & Endorsement type	Training Requirements	Training course cost (Ave.)	Training course contact hours (Ave.)	Number issued (annual)	Total training course cost ($)	Total (hrs)
ACUP						
Standard	AHCCHM303 – Prepare and apply chemicals, and AHCCHM304 – Transport and store chemicals	$360	12 hrs	1351	$486,360	16,212
#Standard and 1080 & PAPP	Above course and 22275VIC Course	$360 + $220 = $580	3 hrs	591	$342,780	1773
Pindone Concentrate	AHCVPT306A, AHCFAU201A, AHCPMG402A and AHCVPT302A	$1500	64 hrs[33]	7	$10,500	448
Fumigant	CPPPMT3011A – Conduct Fumigation	$1200	24 hours	8	$9600	192
CCA	FPISAW3201B - Treat timber	$145	8 hours	1	$145	8
Total ACUP					**$849,385**	**18,633**
COL						
Agricultural Chemicals	AHCCHM303 – Prepare and apply chemicals, and AHCCHM304 - Transport and store chemicals	$360	12 hours	197	$70,920	2364
Vermin Destroyers	AHCVPT306A, AHCFAU201A, AHCPMG402A and AHCVPT302A	$1500	64 hours	8	$12,000	512
1080 & PAPP	22275VIC Course	$220 r	3 hours	44	$9680	132
Fumigant	CPPPMT3011A - Conduct Fumigation	$1200	24 hours	6	$7200	144
CCA	FPISAW3201B - Treat timber	$145	8 hours	3	$435	24
Total COL					**$100,235**	**3176**

Table 6.1 shows that the cash cost of completing a training course for an individual licence/permit applicant is between $145 and $360 in most cases, although courses in respect of a small number of licence/permit categories are in the range of $1200 – $1500. The total cash cost of completing the training requirements is approximately $0.95 million per annum, while the time costs sum to approximately 21,800 hours per annum. If the latter are conservatively valued at the most

[33] Four contact days, plus private study – assumed to be of similar duration.

recent ABS published average weekly ordinary time earnings figure of approximately $39.89 per hour[34], the implicit cost of this time commitment is equal to around $0.87 million.

Thus, the total costs incurred by new licence applicants in meeting the specified training requirements sum to around $1.82 million annually. While detailed data on the remaining licences is not available, the total cost figure would be likely to be in the vicinity of $2.0 million annually.

This training cost data has been included for the sake of completeness. However, the regulations do no more than clarify that non-compliance with the specified training requirements constitutes grounds for the Chief Administrator to refuse a licence/permit application. As noted above, the substantive training requirements are not set through the regulations but, rather, via an order of the Chief Administrator, made pursuant to guidelines published in the Government Gazette.

Given this, DEDJTR does not believe that these training costs can be considered to be attributable to the regulations.

6.5. Aerial spraying costs

The proposed Regulation 16 requires that a person not carry out aerial spraying unless one of a number of specified means of determining the wind direction are used. The specified means are a ground-based smoke generating device, an aircraft mounted smoke generating device, a windsock and a ground-based weather station, the data from which is made available to the pilot.

The RIS in respect of the current regulations calculated the cost of this requirement using the average cost of a smoke generating device. Consultation with the relevant industry association (i.e. the AAAA) indicates that smoke generating devices are now almost invariably used by fixed wing aircraft engaged in chemical spraying, while rotary wing aircraft (i.e. helicopters) typically use ground-based weather stations.

However, the advice received is that fixed wing aircraft operators incur no incremental cost as a result of the requirements of Regulation 16, since smoke generating devices are now fitted as standard equipment to all aerial spraying aircraft supplied by both manufacturers who currently service this market.

In relation to rotary winged aircraft, the advice received is that the widely used *Kestral* device costs in the order of $300-$400. Six operators are believed to use rotary winged aircraft in Victoria, with the total number of such aircraft in use being approximately 12 – 15[35]. This implies a maximum capital cost for these devices of $6000. Other related costs would include the cost of ground-based staff used to convey the relevant whether information to the pilot.

However, the advice received from the AAAA is that rotary winged aircraft used for aerial spraying purposes are invariably accompanied by ground support crew for economic reasons. The relatively high operational cost of these aircraft means that using ground crew able to ensure the aircraft can be resupplied as needed as near as possible to the work site is the cost minimising method of operation.

Given this, the normal mode of operation of rotary-winged aircraft involves the presence of ground crew who are able to relay weather data to pilots as required. Thus, AAAA believes that the regulations do not impose any additional labour costs. Moreover, the advice received is that all users of rotary winged aircraft would employ ground-based weather stations even in the absence of a specific regulatory requirement to this effect, since commercial considerations make it necessary to ensure that spray drift is minimised all times. This is reflected in the fact that operators invariably adopt a formal Spray Drift Management Plan or a broader Risk Management Plan as part of their normal operations.

Given this, it is concluded that the cost of ground-based weather stations represents a business as usual cost, which should not be attributed to the regulations.

Consequently, no incremental costs are attributed to the regulations as a result of these requirements in relation to aerial spraying.

[34] Based on ABS Cat. 6302.0: Average adult full-time ordinary time weekly earnings for May 2016 of $1,516, divided by 38 hours, equals $39.89/hour. Given that the time costs involved are in most cases quite small, it is considered reasonable to avoid adding allowances for on costs and overheads to this hourly figure.

[35] This is an imprecise estimate derived from advice that, nationwide, approximately 130 operators employ around 300 aircraft (of all types) in total.

6.6. Costs of having stock and produce tested

Section 56 of the Act states that an Authorised Officer may require stock or agricultural produce to be tested at the owner's expense under prescribed circumstances. The proposed regulation states that such testing at the owner's expense can be ordered if the owner has or is reasonably suspected of having sold or consigned for slaughter contaminated stock or sold contaminated produce during the past two years, has been found guilty of an offence under section 19 or section 50 of the Act or has been found guilty of an offence under the *Drugs, Poisons and Controlled Substances Act 1981* or the regulations made pursuant to that Act.

A total of seven Testing of Agricultural Produce Notices were issued between 2008 and 2016. Two of these were issued 2012 and five were issued in 2010. Thus, the average number of these notices issued is around one per year. However, no Testing of Stock Notices have been issued in recent years. It is not expected that the proposed regulations will change the number of testing notices issued.

Stock and produce owners will incur these costs only in cases in which they are suspected of selling contaminated stock or produce or have been found guilty of breaching relevant legislation. Thus, these costs must be regarded as being largely avoidable in nature[36].

Consequently, it is concluded that these costs are not attributable to the regulations *per se*.

6.7. Costs of prohibiting possession of certain unregistered chemicals

The creation of a new offence of possession of certain unregistered chemicals will impose a small cost on those licence and permit holders who currently possess stocks of the prohibited chemicals. In most cases, this circumstance will arise because the chemicals in question were previously registered, but have subsequently had the registration withdrawn. As the use of these chemicals is already prohibited, the only identifiable cost associated with the adoption of this prohibition is the cost of disposing appropriately of the affected chemicals.

As noted in section 4, the scope of the proposed prohibition on possession is limited, being focused solely on that group of agricultural chemicals that are considered likely to impose significant risks. Further, historical and on-going government and industry disposal programs are likely to have greatly reduced any remaining on-farm stocks. Consequently, the amount of chemicals that will need to be disposed of in order to ensure compliance is believed to be quite small. DEDJTR officials estimate that the quantity of chemicals involved is likely to be around 200 L, while information sourced from a company engaged in disposal activities suggests that the cost per litre of disposal is likely to be of the order of $50.

The disposal of old unregistered chemicals is often in as a result of property transfers to new landowners and the cost is incurred as a business-as-usual practice. It may therefore be estimated that at least half of the disposal would occur regardless of the regulation.

Hence, the cost impact of this proposed new provision of the regulations is likely to be limited to a one-off cost of around $5,000.

6.8. Regulatory costs

The costs incurred by DEDJTR in administering and enforcing the current regulations are estimated to total $1,384,692 per annum. The following provides a detailed breakdown of these costs.

A total of 10.3 full time equivalent (FTE) staff are engaged in regulatory activities pursuant to the current regulations. The breakdown of these regulatory resource costs is as follows:

- **Processing of licences/permits**: A total of 1.4 FTE are employed in the "Tagroom", which has responsibility for receiving and processing licence and permit applications. In addition, 0.4 FTE of the total of 2.4FTE employed the Biosecurity Assurance branch are employed on licence and permit processing activities.
- **Agricultural services and Biosecurity Operations**: A total of 6.2 FTE are employed in this branch, which is primarily responsible for compliance activities including education, monitoring and enforcement of the Act and regulations.

[36] The only circumstance in which such a cost could not be regarded as avoidable is one in which action to require testing is taken based on a "reasonable suspicion" which subsequently proves unfounded. Given the circumstances of these cases, this is considered by DEDJTR to be likely to be a very rare occurrence.

- **Biosecurity Assurance**: A total of 2.4 FTE are employed in this area, of whom 0.4 FTE are devoted to tasks related to the processing of licence/permit operations, as noted above. This group has responsibility for high level policy development such as development of nationally harmonised approaches to regulation of AgVet chemical use. The relatively smaller portion of their time (0.4 FTE) reflects this commitment. In addition, Biosecurity Assurance fund and manage the Targeted Agchem Residue Program, which monitors compliance with chemical use requirements and fresh produce residue standards.

The average total cost per staff member engaged in the regulatory functions carried out by the "Tagroom" and the Biosecurity Assurance function has been calculated by DEDJTR as $136,492 per annum. This value has been calculated by DEDJTR's Finance Branch as part of internal budgeting processes and is based on a midpoint VPS-4 salary figure of $82,627[37]. It therefore implies total on-costs and overheads of 65.2%, a percentage which is slightly below the VGR "benchmark" level of 75%.

Given this average cost figure, the cost attributable to the regulatory administration functions performed by these groups is equal to:

3.8 x $136,492 = $518,670 per annum.

A slightly higher average cost of $139,681 per FTE has been calculated for the ASBO functions. Based on the 6.2 FTE employed in this area, the total cost associated with this function is equal to:

6.2 x $139,681 = $866,022 per annum.

Summing these two costs gives a total cost for DEDJTR's regulatory administration and enforcement functions in the chemicals area of:

$866,022 + $518,670 = $1,384,692 per annum.

6.8.1. Cost recovery

A proportion of the regulatory costs identified above are recovered from the users of the regulated chemicals through the imposition of licence and permit fees. Importantly, only a proportion of the costs associated with the regulation of agricultural and veterinary chemicals are incurred in regulating licence and permit-holders. These costs may be reflected in several areas, for example must still undertake compliance activities relating to uses of agricultural and veterinary chemicals that do not require authorisation via a permit or licence. These could include responding to enquiries regarding on-label use of chemicals which do not require permits, provision of information to the general public, addressing permit/licensing enquiries which don't result in a permit/licence being issued and also, development of high level policy advice which is not considered cost recoverable. Consequently, it is not appropriate to seek to recover the full amount of the costs identified above from this group. DEDJTR estimates, based on an informal review of the activities undertaken by the relevant sections, that $1.0 million of the approximately $1.4 million or approximately 70 per cent in annual costs identified above is attributable to licence and permit-holders.

Current fee revenue is approximately $0.3 million per annum, suggesting that only around 30% of the costs attributable to licence and permit-holders are currently being recovered. This reflects the fact that the licence and permit fees charged have not been reviewed since December 2004 and were not initially set on the basis of a rigorous cost-recovery based analysis. DEDJTR is currently reviewing the licence and permit fees in light of the new analysis of its regulatory costs summarised above and expects to introduce a new fee structure in late-2017 or early 2018. However, it should be noted that the licence and permit fees are not established as part of the regulations. Rather, they are made via a Ministerial Notice. It is therefore intended that a new Ministerial Notice will be published which will likely require further stakeholder consultation and possible development of a separate RIS to support this process.

[37] This reflects the fact that the majority of staff engaged in activities related to the regulations are employed at VPS-4 level.

6.9. Cost summary

Table 6.2 summarises the costs associated with the regulations, as set out above.

Table 6.2: Summary of Regulatory Costs

Cost item	Total
Record-keeping	$1,147,645
Labelling	$990,000
Notifying aerial spraying	$2,325
Licensing	Not attributable ($2.0m p.a. but attributed to Ministerial Order specifying training requirements)
Aerial spraying	$0
Stock and produce testing	Not attributable
Disposal of unregistered chemicals	$5,000 (one-off)
Regulatory administration	$1,384,692
Total (p.a.)	**$3,490,771**
Total (Present value over 10 years)	**$28.3 million**

Table 6.2 shows that the estimated annual cost of the regulations is approximately $3.5 million, which is equivalent to a present value of $28.3 million over 10 years, using a standard 4% discount rate. As indicated, the training costs associated with licensing and permitting account for a further $2.0 million per annum, but the Department does not consider them to be attributable to the regulations, since the training requirements which constitute their core element are established via a Ministerial Order, rather than via the regulations.

7. IDENTIFICATION AND ASSESSMENT OF FEASIBLE ALTERNATIVES

7.1. Overview

The range of feasible alternatives that can be considered in the context of the proposed regulations is significantly constrained by the broader regulatory environment. These include international norms in the regulation of agricultural and veterinary chemicals and Victoria's position as a partner in the National Registration Scheme for these chemicals.

A key consideration in relation to the latter point is that the regulatory model for a single national framework for the regulation of agricultural chemicals and veterinary medicines, which was adopted in 2013 and subsequently endorsed via intergovernmental agreement, places obligations on Victoria to maintain regulatory requirements in key areas addressed in the current and proposed regulations, notably record keeping and licencing of commercial users. These inter-governmental agreements not only oblige Victoria to continue to regulate in these areas, but also specify that the content of the regulatory requirements adopted must be consistent with the approach identified in the national model and adopted by all other jurisdictions.

Given this regulatory context, the options that can feasibly be considered essentially involve the adoption of different approaches in relation to individual elements of the regulations, including changes at the margin to the scope of the regulations. The following sets out key options that have been considered during the development of the proposed regulations but not adopted and summarises the benefits and costs of each.

7.2. Adopt a performance-based regulation in relation to spray drift management

Description of the alternative

Proposed Regulation 16 has the objective of ensuring that a pilot conducting aerial spraying has adequate information as to wind direction and strength at the time that spraying is undertaken. The current regulations require that one or more of four specific sources of information must be available, while the proposed regulations add a fifth option.

This is an essentially prescriptive approach. A feasible alternative to achieving the objective sought by the regulation is to instead adopt a performance standard, along the following lines:

> *"A pilot must ensure that he/she has sufficient information regarding wind speed and direction at the time that spraying is conducted to enable him/her to ensure that spray drift is avoided."*

Expected benefits of the alternative

Performance-based regulation is typically adopted as a means of clarifying the underlying regulatory objective and allowing regulated parties flexibility in determining the most effective and cost efficient means of complying with regulatory requirements. This helps to ensure that specific, prescriptive regulatory requirements do not rule out new and innovative approaches to achieving the underlying regulatory objective and can, therefore, tend to reduce regulatory compliance costs over time, particularly where regulations are not frequently reviewed and amended.

As noted above, the proposed regulations include an additional mechanism by which pilots are able to inform themselves as to wind speed and direction, involving communication of this information from a ground-based weather station. This change to the existing regulations is expected to enable helicopter pilots to comply with the regulation in a lower cost matter and, in itself, can be seen as demonstrating the need for regulation to be able to accommodate new techniques and technologies in the interests of efficiency.

To the extent that the industry is able to identify new and more effective and/or lower cost means of obtaining the required information during the life of the proposed regulations, adopting a performance-based requirement could yield substantive cost savings.

Expected costs of the alternative

Regulated parties frequently expressed concern that performance-based regulation yields a lack of certainty as to compliance. That is, it is not always clear whether a particular course of action will be accepted by regulators as being compliant with the performance based regulatory requirement. This issue is also of concern to the expected beneficiaries of the regulations (in this case, occupiers of surrounding land) in some cases. That is, concerns can arise that regulated groups will not take sufficiently robust steps to ensure that the regulatory objective is achieved.

However, this issue can be mitigated if prescriptive guidance with "deemed to comply" status is incorporated along with the performance based regulatory requirement. In the current context, this could imply supplementing the regulatory requirement that the pilot have sufficient information on wind speed and direction to enable spray drift to be avoided with "deemed to comply" provisions covering the four currently permitted sources of information on wind speed and direction, as well as the additional, proposed source of this information.

Assessment of benefits and costs

The proposed regulations, while remaining prescriptive, provide five different options to ensure that information on wind speed and direction is available to the pilot. Moreover, DEDJTR notes that the advice received from the aerial spraying industry (and summarised in section 6.5, above) is that the current regulatory requirements, supplemented by the proposed additional compliance option, will not impose any incremental cost burden on its members. That is, the "business as usual" costs incurred by the industry for commercial and other reasons include ensuring information provision in ways that are compliant with the proposed regulations.

Given this, there do not appear to be significant opportunities for cost savings to be realised through the adoption of a performance-based regulatory requirement. Equally, the industry has not suggested that potentially more effective mechanisms are currently being ruled out by the existing regulatory requirements.

Despite this, DEDJTR believes that there is some potential for a move toward a performance-based regulation to be made, while adequately addressing concerns within the community as to whether appropriate standards would be met in practice. However, such an option would need to be carefully designed and implemented in order to prevent any potential loss of community confidence in the safety of aerial spraying activities, which could have negative implications for both the aerial spraying industry and landholders who use their services.

On balance, therefore, it is intended to retain the existing prescriptive approach at the present time, albeit amended as discussed in sections 4 and 5, above. However, DEDJTR seeks the views of relevant stakeholders, including land holders, the aerial spraying industry and concerned community members, on this issue.

Stakeholder questions: *Do you believe that moving to performance-based requirements in relation to aerial spraying information is appropriate? If so, should such a regulation include "deemed to comply guidance"? What do you believe would be the key benefits of moving to a performance-based requirement? Alternatively, if you are opposed to the adoption of a performance-based regulation, what do you see as the major problems likely to arise?*

7.3. Removing the notification requirement for spraying by air or mister

Description of the alternative

The requirement for landholders to notify schools, hospitals, childcare and aged care facilities located within 200m of land to be sprayed by aircraft or mister is a relatively recent one, having been incorporated into the current regulations in 2007. As discussed above, the requirement to use appropriate equipment to detect wind speed and direction and thus ensure that spray drift is avoided, arguably means that the notification requirement is unnecessary.

It can also be argued that other, more general, legislation exists which is relevant to the aerial spraying and provides disincentives to poor practice and a basis for those responsible for use near sensitive sites to have confidence that good practice will be followed. These include controls under the *Occupational Health & Safety Act 2004* that provide duties of employers to other persons not to expose them to risks to their health or safety arising from the conduct of the undertaking of the employer and the possibility of enforcement action being taken under the *Environment Protection Act 1970* in response to spray drift.

Another factor is that the nature and the extent of the risk posed by spray drift varies substantially, depending on the nature of the chemical being sprayed and the method of application. The APVMA is progressively introducing a comprehensive risk based assessment framework to provide enforceable label directions such as downwind buffer zones that are relevant for each chemical product, which will greatly improve information available to users to manage spray drift. It will also improve the ability for regulators to hold users accountable if they do not follow the label directions. The expected adoption of this additional risk-management approach as also supports the view that a notification requirement is no longer required.

Consultation with aerial sprayers also indicated some concern that the notification requirement poses practical difficulties, in that it is sometimes necessary to schedule spraying activity at short notice to take advantage of changes in wind speed or direction and thus avoid spray drift issues.

Given these factors, consideration was given as to whether the regulations should be remade without including the notification requirement for aerial spraying.

Expected benefits of the alternative

The clearest benefit of removing the notification requirement lies in the time saving for land-owners of no longer needing to undertake this activity. As discussed above, it is anticipated that this saving would be a small one, as the regulations do not specify the form in which notices are to be given and, as a result, a simple phone call is be sufficient to achieve compliance. As discussed in section 6, the best available information suggests that, in practice, the notification requirements are triggered in only a small proportion of cases of agricultural spraying, as there will often be no affected use (i.e. hospital, school, aged-care facility) within 200m of the relevant crop to be sprayed.

Reflecting this, the annual cost of complying with the notification requirement was estimated in section 6 as $2325 per annum. This constitutes the best valuation of the time saving that land owners would incur were this option to be adopted.

A potentially more significant benefit lies in the fact that brief opportunities to undertake spraying arising due to weather changes would not be lost due to inability to undertake notification requirements within the time available, noting that notification must occur at least 24 hours before spraying commences. However, as it is unlikely that appropriate weather conditions for spraying would not recur relatively frequently, DEDJTR believes that this is not likely to constitute a significant benefit in practice.

It is also arguable that the presence of the notification requirement could, itself, have perverse effects. That is, while it is intended to enhance public confidence by providing transparency in relation to spraying and allowing managers of the relevant facilities to take measures in response, it is possible that an unintended impact of the notification requirement may be to increase the level of public concern regarding crop spraying by heightening perceptions of the risks involved.

Expected costs of the alternative

Removing the notification requirement would have several identifiable costs. A key factor is that DEDJTR believes that the alternative mechanisms discussed above have limited capacity to substitute for the notification requirement. In particular:

- While the APVMA labelling initiative discussed above may potentially be significant in enhancing public confidence regarding the risks of aerial spraying, their comprehensive risk based framework for managing spray drift has, to date, been only partially implemented, the majority of labels to not include the new spray drift directions; and
- While actions available under the *Occupational Health and Safety Act 2004* or the *Environment Protection Act 1970* constitute feasible responses to actual incidents of spray drift, these other Acts do not directly and explicitly address potential harms or concerns associated with spraying. The general nature and infrequent enforcement of protections under these Acts with respect to spray drift may limit the deterrent effect in practice. In addition, these Acts do not address the right to know and public confidence issues that underpin the notification provisions.

As noted above, the notification provisions can be seen as an additional risk management practice that allows occupants at those sites to take precautions and seek advice on health risks in the event that the chemical user fails to prevent spraydrift, or in anticipation of this possibility. Removing the notification requirement would limit the ability of sensitive users nearby to take such actions. By implication, it may increase the general level of concern regarding the use of aerial spraying and ground-based misters.

Table 2.4, above, shows that there are around 45 calls per annum, on average, to the DEDJTR Customer Service Centre in relation to concerns regarding spray drift, a number that has remained roughly constant over the past decade. This number of calls underlines the fact that there are real concerns in relation to spray drift, which can be considered sufficient to justify requiring additional, low-cost steps to be undertaken to alert potentially vulnerable groups to the possibility of spray drift occurring and allow them to take appropriate countermeasures.

Assessment of benefits and costs

DEDJTR considers it appropriate, to retain the notification requirements in relation to aerial spraying and the use of misters. This conclusion reflects, in large part, the combination of the low costs identified in association with this regulatory requirement and the potentially significant benefits in terms of the maintenance of public confidence which the notification process may confer. In particular, providing potentially vulnerable populations with the opportunity to take steps to further reduce the risks of any exposure to spray drift may provide important benefits to these groups.

That said, the merits of this aspect of the regulations will necessarily be kept under review, particularly in the light of future trends in terms of spray drift investigations and the potential implementation of the APVMA labelling and related initiatives discussed above.

7.4. Adopt a compulsory reporting requirement for laboratories that detect contaminated produce

A proposal considered during the development of the regulations was to introduce a compulsory reporting requirement for laboratories that detect contaminated produce. Laboratories would be required to notify DEDJTR of the detection of contaminated produce within a specified time period.

Expected benefits of the alternative

The key benefit of including such a requirement in the regulations is that it can be expected to enhance the ability of DEDJTR and other relevant authorities to respond to incidents of contamination of produce in a timely and effective manner, since they will be assured of being notified that contamination has occurred immediately upon its discovery. This has the potential to reduce harms due to contamination by, for example, helping to ensure that contaminated products are not exported and do not cause market access problems (as discussed in Section 2).

Expected costs of the alternative

The key costs associated with this initiative is that, if undertaken at the present time, it would create a situation where Queensland and Victoria would be the only Australian jurisdictions to adopt such a requirement. This could have a number of negative implications.

First, it would potentially create confusion within the laboratory sector as to the applicability of these obligations. For example, questions would arise as to whether a laboratory located in New South Wales, South Australia, which was undertaking work for a Victorian-based client would be subject to the compulsory recording requirement.

Second, it is possible that adopting a Victoria specific requirement could yield distortions in the market, with producers or other parties choosing to use interstate laboratories to avoid compulsory reporting should contamination be found in produce. This could reduce the effectiveness of the initiative, while testing laboratories in Victoria could be disadvantaged.

Assessment of benefits and costs

It should be noted that work toward the adoption of an Australia wide compulsory reporting requirement has been underway within national bodies responsible for the regulation of agricultural and veterinary chemicals for some time and that it is expected that such a national requirement will, in time, be adopted.

In this context, DEDJTR has taken the view that it is preferable to await the implementation of a national requirement, since this can be expected to be more effective overall and to avoid the potential problems identified above.

Stakeholder questions: *Do you believe that compulsory reporting of contaminated produce should be adopted nationally? Do you believe that a state-based scheme would be desirable in the absence of a national approach? If so, why? What issues of concern could arise with a state-based approach?*

7.5. Adopt a general prohibition on possession of unregistered AgVet chemicals

Description of the alternative

An alternative approach to the proposed prohibition on the possession of certain, specified unregistered AgVet chemicals would be to broaden the proposed prohibition to include all unregistered AgVet chemicals, rather than limiting it to the seven, particularly dangerous chemicals identified in the proposed regulations. The offence of possession could commence after a suitable time period, to allow disposal to occur.

Expected benefits of the alternative

As discussed in section 5, the proposed prohibition is intended to reduce the potential for harms to arise due to the inappropriate use of these chemicals, whether deliberate or inadvertent, or due to leakages, spillages or other accidents, giving rise to harms to the environment, including native animals, or to stock and/or persons. Clearly, adopting a generalised prohibition on the possession of unregistered AgVet chemicals could yield additional harm reduction benefits.

That said, DEDJTR has little available information as to the frequency and extent of harms arising from the misuse of unregistered AgVet chemicals. Thus, it is difficult to determine to what extent this option would provide additional benefits in practice.

Nonetheless, as a general comment, there is merit in adopting an approach which should ensure that chemicals that are no longer authorised to be used are removed from the environment within a relatively short period. Moreover, the adoption of a broad prohibition covering unregistered AgVet chemicals would arguably provide a clear signal to regulated parties as to their obligations in this regard. It would also be consistent with the regulatory requirements currently in place in the adjoining jurisdictions of South Australia and New South Wales. This would make compliance requirements clearer and easier for persons holding AgVet chemicals in multiple jurisdictions.

Expected costs of the alternative

It was estimated above that the partial prohibition contained in the proposed regulations is likely to impose a one-off compliance cost of around $5,000. This total prohibition option would be expected to lead to significantly higher one-off costs, as a much greater range of chemicals would be expected to require disposal. DEDJTR does not have sufficient information available to enable estimation of this cost. However, it is plausible that it could be in the range of $50,000 - $100,000.

To some extent, the identified disposal costs can be considered to be gross costs. That is, older chemicals will generally be disposed of eventually in the absence of any specific regulatory requirement, as a result of normal business management practices. The existence of the industry funded ChemClear program necessarily reinforces this dynamic. To this extent, the impact of adopting a prohibition on possession would be to bring forward the disposal date and the associated costs and the above costs should be discounted accordingly.

A further cost of adopting a blanket prohibition on possessing unregistered AgVet chemicals is that it would place a greater obligation on DEDJTR to monitor and enforce compliance with this requirement.

Assessment of benefits and costs

DEDJTR considers that, in light of the existing regulatory requirements and incentives such the industry ChemClear program, a selective approach to this issue constitutes the more proportionate approach to risk management. However, stakeholder views are sought on this issue.

Stakeholder questions: *Do you believe that a general prohibition on the possession of unregistered AgVet chemicals should be adopted? If so, what do you see as the cost implications of such a prohibition? Alternatively, are there specific chemicals that you believe should be added to the proposed list of prohibited chemicals?*

8. CONCLUSION

The preceding discussion identifies the role of the existing, and proposed, regulations within the wider context of state and Federal agricultural and veterinary chemicals legislation and explains the contribution the current regulations make to the larger regulatory structure, and its goals. In particular, it has linked the provisions of the current and proposed regulations to mechanisms by which the potential harms associated with chemical use can occur.

The Department considers that the costs of the proposed regulations are modest, being estimated to total $3.5 million per annum. It has not proven possible to quantify some of the specific benefits provided by the current regulations. This reflects, in part, the fact that many of the benefits involved, such as the prevention of harms to native species, are difficult to quantify in dollar terms. It also reflects the closely interwoven nature of these regulations and the wider (national) regulatory structure.

That said, section 2.3 has highlighted the fact that even a small number of incidents of contamination of stock or produce can give rise to substantial economic costs due to the potential for restrictions to be placed on market access for producers, in particular, export markets. Several elements of the current and proposed regulations provide specific tools to assist in addressing the problem of contamination, both in terms of reducing the likelihood of its occurrence and in terms of providing information to regulators to enable incidents to be addressed in a timely and effective fashion, thus minimising risks to market access.

Moreover, to the extent that the regulations contribute to the safeguarding of human health, the modest annual costs identified above are most likely to be more than offset by benefits[38].

Given these factors, DEDJTR is confident that the benefits conferred by the current and proposed regulations significantly exceed the identified costs.

A second perspective on this issue is consideration of the proportionality of the costs identified. This question of proportionality can be considered in relation to the overall benefits of the use of agricultural and veterinary chemicals: section 1, above, included an estimate that the benefits to Victorian agriculture of the use of these chemicals, are likely to be of the order of $2.9 billion per annum. The identified regulatory costs represent slightly more than 0.1% of this total.

Another approach to considering the question of proportionality lies in comparing the identified costs with the number of licence and permit holders. There are approximately 21,400 licence and permit holders in Victoria. The identified cost of $3.5 million per annum therefore represents an annual cost of approximately $163.55 per licence and permit holder. Importantly, it should be noted that many users of agricultural and veterinary chemicals are not licence or permit holders and that the beneficiaries of regulation in this field also extend far beyond this group.

Given this, DEDJTR believes that the expected benefits of the proposed regulations will substantially outweigh the identified costs.

Finally, section 7 has made the case that the range of feasible alternatives to the proposed regulations is necessarily very narrow, given their role as part of a much larger legislative structure. A number of specific variants to the proposed regulations which were identified during the review of the current regulations and development of this RIS have been identified and assessed in terms of their benefits and costs. In each case, it has been concluded that these potential initiatives should not proceed as, on balance, the costs that they were imposed are considered likely to exceed the associated benefits.

Accordingly, the Department intends to proceed with the making of the proposed regulations, subject to the results of consultation to be undertaken on the basis of this RIS. As part of this consultation, the department is seeking responses to the specific stakeholder questions identified in the text of this RIS. This includes questions relating to the assessment of the relative merits of the various alternatives identified above.

[38] Noting, in particular, that a standard Value of a Statistical Life (VSL) exceeds $4 million.

9. CONSULTATION

Preliminary consultation was undertaken with a total of 88 stakeholders between September and December 2016. This involved a written request for feedback to be provided on the current regulations, as well as proposals for changes to the regulations.

Comments were received from the following stakeholders:

- Veterinary Practitioners Registration Board of Victoria & Australian Veterinary Association
- Australian Veterinary Association
- Stock Feed Manufacturers Council of Australia
- Aerial Application Association of Australia
- CropLife
- Victorian Groundsprayers Association
- Invasive Species Council
- Australasian Land & Groundwater Association
- Victorian Farmers Federation

Table 9.1 summarises the main views expressed and DEDJTR's response. While some of the views received addressed issues beyond the scope of the regulations, the response is restricted to those comments that relate directly to the issues arising in respect of the remaking of the regulations.

Table 9.1: Summary of stakeholder comments received

Comment	DEDJTR Response
Regulations do not directly relate to the use of Schedule 4 Poisons within animal feeds (i.e. use in feed mills where the feed is supplied under veterinary order to livestock owners). Clarification was thus requested as to whether the record keeping requirements under reg. 6 apply in this context or should be exempted in feeds manufactured under veterinary orders as controlled by the *Drugs, Poisons and Controlled Substances Regulations 2006*.	Use, in this context, refers to the point at which the product is administered, fed, or applied to animal(s) ; not when product is mixed by manufacturer. Therefore R6 does not apply to stockfeed manufacturers. Rather, requirements for manufactures are covered under the DPCS Act. DEDJTR will communicate with affected parties to ensure that this position is widely understood.
Record keeping is complex and costly in and requires continuous administration and that differing record keeping requirements add to the complexity of maintaining records, particularly for operators who conduct applications in more than one State or Territory. It was argued that Victoria should work closely with neighbouring states to standardise and simplify record keeping while still supporting transparency and accountability.	Agree. Victoria is leading national harmonisation of agricultural chemical use record keeping. The changes proposed to record keeping requirements in the draft regulations reflect this intention and move towards more harmonised national record keeping.
While we support a move towards nationally consistent record keeping, we are concerned about the potential for reduced record keeping requirements in Victoria to have flow on impacts on our ability to maintain our access arrangement to off label chemical use	The proposed record keeping requirements do not necessitate Victoria to change the access arrangements for to off label chemical use.

Comment	DEDJTR Response
Regulation must be cognisant of technological advances and their adoption by Victorian farmers and other land managers, particularly with regard to record keeping. The Regulation must also be outcome focused, rather than adopting prescriptive approaches which can rapidly become outdated. Systems that can replace the need for manual paper based systems prone to human error and provide more accurate, timely and auditable information should be promoted within the Regulation.	Support in principle. Proposed record keeping will recognise elements collected and maintained electronically.
Given the use of electronic databases in conjunction with written records is it necessary to record the names & addresses of the applicator and client these details on every spray record sheet. This is considered unnecessarily burdensome as, provided there is something to tie in with the details back at the office, adequate traceability is maintained. A client's normal name e.g. Bill Carter or even a nickname such as `Alfie' is fine because all the details are on office computer.	Agree. Record keeping elements do not need to be consolidated in one format or location. The use of nicknames or other codes on a spray record sheet are acceptable provided they can be clearly linked to other records.
The requirement to record the specific location of the paddock treated is unnecessarily burdensome. The only time this item is relevant is if something goes wrong. (Same can be said for the records per se.) If something goes wrong the location of the paddock is well and truly known without reference to a spray record. Particularly if a farmer is spraying his own paddocks. (Remember that these regulations go back to late fifties, early sixties last century and applied to aerial application only.)	The "Specific location at which the product was used" is a proposed record keeping element for agricultural chemicals. The description must be sufficient to enable the treated area to be identified by a person not familiar with the location. This is important for enforcement and investigating adverse experience.
Records of use of veterinary chemical products. Under of other regulations, collection of this information is required of livestock producers using HGPs already. A model should be considered that captures this data, but does not duplicate.	Agree. Hormonal Growth Promotants (HGP) users will no longer need to keep records associated with supply and possession as these records are covered under national supply arrangements.
A land occupier, for the purposes of reg. 12, can be different to the person who has commissioned the aerial spraying. For example, the occupier may be a corporation or absentee owner.	The regulations include requirements for the occupier of land. The definition of "occupier of land" is covered by the ordinary meaning. This person will vary depending on the land use, but should be a natural person or corporation who has day to day control and management of the land. In the case of a farm manager employed by a corporation, accountability may also reside with the corporation via the vicarious liability provisions in the Act. Land owners leasing the land to another party for agricultural purposes would not be considered to be the land occupier.

Comment	DEDJTR Response
The notification requirements under reg. 12(3) could be interpreted to mean that, if a contracted sprayer arrives at a treatment area and identify services of the kind requiring notification prior to conduct spraying, they must obtain notification from the land occupier. Subsequently the sprayer is obliged to avoid spraying until notification is received as per subregulation (1). **Recommendation**: Remove the responsibility of the aerial applicator to notify the occupier, under sub regulation (3), ensuring that the responsibility is solely with the land occupier or person who has commissioned the spraying.	Agree. The proposed regulation amends existing regulation 12 in a manner consistent with this proposal. The emphasis of the regulation is rightly on the responsibility of the land occupier. However, it should be considered that the professional expertise of aerial spraying operators means there should be an expectation that they do not knowingly conduct spraying within 200m of a sensitive service without enabling notification to occur.
The requirement for users of all pesticides to provide notifications prior to use when application is to occur within 200 meters of a 'sensitive area' fails to recognise the comprehensive risk based assessment framework of the APVMA. It implies that all pesticides are hazardous and that every application will result in exposure to the sensitive area. This is not the case and therefore this regulation can result in a perverse outcome whereby those notified regularly assume all pesticide applications have the same level of risk. This assumption can lead to complacency and when the APVMA determines that a pesticide application actually has a risk that requires mitigation, this complacency may result in people not taking the proper precautions required by the APVMA. Regulation 12 is unnecessary and consideration to its removal is recommended.	Disagree. The proposed regulation does not imply that every application will result in exposure to the sensitive area. However, it should be noted that many pesticides are classified as hazardous substances. The proposed regulation provides a mechanism for information to be provided to the manager of these sites to allow them to make decisions regarding the appropriate care of the site's occupants. Knowing the trade name of the agricultural chemical will allow the manager of the site to access safety data for the agricultural chemical product proposed to be used. This can be used to help determine what (if any) actions may be necessary. Spraying by aircraft or mister is not likely to be frequently experienced by any of the groups in question. As few products have been registered through the APVMA spraydrift operating principles, there is insufficient information on most labels to adequately manage spray drift risk through reliance on following label instructions.
The list of approved aerial spraying equipment does not allow for ground based crews to provide information directly to the pilot on weather conditions. Industry best practice sees these ground based persons being equipped with a handheld anemometer, colloquially known by a popular brand name as a "kestrel" or a vehicle mounted weather station. Additionally a length of marking tape mounted on the support vehicle to provide a visual indication of direction is often used in conjunction with a visual inspection utilising the Beaufort scale. The regulations fail to identify the important role the support person can provide by monitoring weather conditions both before and during application. **Recommendation:** Provide a fifth acceptable means of compliance: Operations conducted with a ground based person with a means to measure the wind speed and direction and who is in continuous radio communication with the pilot of the aircraft immediately before and during the application. Aircraft is defined as including both fixed wing and rotary wing.	Agree. Additional means of compliance with existing regulation have been adopted in the proposed regulation.

Comment	DEDJTR Response
Will costs associated with contracting an aerial sprayer increase if an additional person is needed to be employed to carry out the weather monitoring task.	There should be no additional costs as a result of the proposal to add an additional means to comply when the pilot is in continuous radio communication before and during the spraying with a ground based person near the point of spraying who uses equipment to measure the wind speed and direction. This means is likely to be utilised in circumstances such as helicopter operations where ground crews are already used.
It was argued that, in the interests of equity, ground applicators should be subject to similar competency, licensing, notification and record keeping arrangements as aerial applicators.	Agree in principle. However, there are inherent differences in the risks and other considerations associated with different application methods that may warrant differences in the regulatory requirements applicable to the two groups.
The review of the Regulation must address commitments to national harmonisation arising from the Intergovernmental Agreement on Agricultural and Veterinary Chemicals.	Agreed. The proposed regulations will comply with the intergovernmental agreement provisions for harmonisation.
The requirement for notification of spraying should be deleted, as spraying is required to be contained within the target area, regardless of location or surrounds.	Disagree. Unfortunately spraying may not always be contained within target area. The purpose of the notification requirements is to minimise this risk in the most sensitive sites.
The chemicals subject to regulation can be used to achieve important environmental outcomes such as pest, disease and weed control. We would encourage greater recognition of the environmental benefit of the chemicals subject to regulation. This could be done by including the word 'environmental' in the name of the regulation and specifically acknowledging the public good of the use of chemicals for environmental purposes.	It should be noted that the purpose of the Act includes protecting the environment. Given the wide focus of the regulations it would not be appropriate to include ‘environmental’ in the name of the proposed regulation or specifically acknowledging the public good of the use of chemicals for environmental purposes in the proposed regulation.
There are concerns from land managers and contractors that the regulations appear to be unnecessarily complex, too risk adverse and do not properly consider the environmental benefit arising. As a result many land managers feel like the conditions on using these chemical options make them impractical or too costly to use, with a resulting environmental impact. The use of many chemicals by volunteers and landholders can be too onerous to make them practical to use due to current regulations.	Victoria’s regulatory controls must manage harms caused by agvet chemical product use. This may require restricting who and how products can be used. The proposed record keeping requirements will explicitly enable a person such as a volunteer coordinator to make records on behalf of the user.
A requirement for notification by commercial laboratories should be nationally consistent rather than state based regulations. Under any future approach, an exemption from any such reporting should be provided for when growers are conducting trials of withholding period requirements for off label use.	Reform to the national approach of monitoring chemical residues in produce are being considered. This could include an Australian wide compulsory reporting requirement. At this stage Victoria is not proposing to introduce a new regulation requiring this reporting until there is a nationally agreed position on this issue.

Comment	DEDJTR Response
Will the prescribed chemical products to be used in accordance with instructions on label or a permit include the nationally agreed 'General conditions of allowed variation on label instructions' as this does not differentiate between restricted chemicals or any other chemical class.	The 'general conditions of allowed variation on label instructions' is a nationally agreed minimum harmonised chemical access model. Under this model, variation includes: a. use at a lower rate or concentration than label instruction or permit condition. b. use for different pest than provided on label instruction or permit condition. c. use at a lesser frequency or longer period between applications. d. applied mixed with another chemical or substance. The allowance of these agreed variations to the chemicals prescribed in the regulations is outside the scope of the regulations will be considered following remaking the regulations.
We suggest that the goal of full cost recovery should not apply to the use of chemicals for environmental benefit. There is a clear public good from the correct use of chemicals to undertake pest and weed control to assist native animals and plants. This public good should be recognised in the pricing and regulation necessary for using these chemicals.	Reforms of cost recovery for licences and permits under the Act will be considered following remaking the regulations. The Victorian Government Cost Recovery Guidelines include charging considerations with respect to public goods.
It seems reasonable that there is cost recovery and that farmers who mis-use products should have to pay for monitoring to ensure that products are not further being mis-used. But it will need better definition around "mis-use" and the regulations need significant tightening up.	Prescribed reasons where testing is to be undertaken at the expense of the owner are defined in the proposed regulations. Reforms of cost recovery for licences and permits under the Act will be considered following remaking the regulations.

10. STATEMENT OF COMPLIANCE WITH NATIONAL COMPETITION POLICY

The National Competition Policy Agreements set out specific requirements with regard to all new legislation adopted by jurisdictions that are party to the agreements. Clause 5(1) of the Competition Principles Agreement sets out the basic principle that must be applied to both existing legislation, under the legislative review process, and to proposed legislation:

The guiding principle is that legislation (including Acts, enactments, Ordinances or Regulations) should not restrict competition unless it can be demonstrated that:

(a) The benefits of the restriction to the community as a whole outweigh the costs; and

(b) The objectives of the regulation can only be achieved by restricting competition.

Clause 5(5) provides a specific obligation on parties to the agreement with regard to newly proposed legislation:

Each party will require proposals for new legislation that restricts competition to be accompanied by evidence that the restriction is consistent with the principle set out in sub-clause (1).[39]

Therefore, all RIS must provide evidence that the proposed regulatory instrument is consistent with these National Competition Policy obligations. The OECD *Competition Assessment Toolkit*[40] provides a checklist for identifying potentially significant negative impact on competition in the RIA context. This is based on the following four questions:

- Does the proposed regulation limit the number or range of suppliers?
- Does the proposed regulation limit the ability of suppliers to compete?
- Does the proposed regulation limit to the incentives for suppliers to compete?
- Does the proposed regulation limit the choices and information available to consumers?

According to the OECD, if all four of these questions can be answered in the negative, it is unlikely that the proposed regulations will have any significant negative impact on competition and further investigation of competition impacts is not likely to be warranted.

The proposed regulations do not explicitly limit the number of users of agricultural and veterinary chemicals or the number of suppliers of these substances, nor do they limit the ability or incentives for suppliers to compete. It is clear that the existence of a system of licences and permits does have a tendency to limit entry into the market to some extent. However, the system of licences and permits is established in the Act, rather than the regulations themselves.

In summary, DEDJTR believes that the proposed regulations do not impose any substantive restrictions on competition.

11. MONITORING AND ENFORCEMENT

11.1. Implementation Plan & Evaluation Strategy

DEDJTR is committed to effective and contemporary regulation consistent with the expectations of the DEDJTR Biosecurity Compliance Strategy (2016-19) of which the proposed regulations form a part. The Biosecurity Compliance Strategy (the Strategy) sets out DEDJTR's approach to executing its compliance responsibilities in relation to biosecurity legislation, describing the compliance philosophy and objectives and the risk management framework adopted.

As discussed above, DEDJTR undertakes regular compliance monitoring in respect of the current regulations. This includes a mix of random and targeted audits of licence and permit holders or other chemical users. Monitoring of chemical residues in produce is also used to detect the misuse of chemicals and verify compliance with residue standards. Investigations are undertaken in response to complaints or other information received. This includes issues related to aerial spraying and the associated notification requirements. Section 2 also sets out details of enforcement actions undertaken in a range of areas.

Given that the proposed regulations are broadly similar in their structure, nature and extent to the existing regulations, it is intended that the current arrangements in these areas will be continued. Specific additions to these current arrangements

[39] *Competition Principles Agreement*, Clause 5. 1995. See: www.ncc.gov.au

[40] See OECD (2011) *Competition Assessment Toolkit. Volume 1: Principles,* pp 8-9. OECD, Paris, 2011.

will be adopted in relation to areas in which substantive changes have been proposed to the existing regulations. In particular, the proposed prohibition on the possession of a range of specified, unregistered AgVet chemicals will need to be monitored in order to ensure that affected parties are complying with these new obligations. This will take the form of monitoring the disposal of these chemicals and assessing disposal levels against estimates as to the quantities currently held.

In addition, the use of the proposed new powers to require the testing of stock or produce at the owner's expense where there is "reasonable suspicion" that they have consigned contaminated stock or produce for sale will be monitored to ensure that this change does not result in issues of concern regarding individual rights.

More generally, DEDJTR Biosecurity will continue to interact with key regulated stakeholders to ensure the proposed changes to the current regulations, while relatively minor, are effectively implemented and monitored to ensure they remain contemporary.