Australian Government

Department of Agriculture

REDUCING THE REGULATION OF STOCK FOOD AND PET FOOD

REGULATION IMPACT STATEMENT

OFFICE OF BEST PRACTICE REGULATION ID NO. 16908

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CONTENTS

Glossary

ABARES	Australian Bureau of Agricultural and Resource Economics and Sciences
AGGR	Australian Government Guide to Regulation
agvet chemicals	agricultural chemicals and veterinary medicines
Agvet Code	Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994*
APVMA	Australian Pesticides and Veterinary Medicines Authority
Code Regulations	Agricultural and Veterinary Chemicals Code Regulations 1995
FIAAA	Feed Ingredients and Additives Association of Australia
FY	Financial year
GMP	Good manufacturing practice
NRS	National Registration Scheme for Agricultural and Veterinary Chemicals
OBPR	Officer of Best Practice Regulation
OPC	Office of Parliamentary Counsel
PFIAA	Pet Food Industry Association of Australia
RBM	Regulatory burden measure—a framework for measuring the burden of regulation mandated by the Department of Prime Minister and Cabinet
RIS	Regulation impact statement
SNAC Order	Veterinary Chemical Products (Excluded Stockfood Non-active Constituents) Order
SFMCA	Stock Feed Manufacturers Council of Australia
Stock food	food for animals, includes foods for livestock and non-livestock species (for example pets, working animals, show animals and equestrian sports)
the department (unless otherwise stated)	Australian Government Department of Agriculture
VCP	veterinary chemical product

Section 1: About this regulation impact statement

1.1 Purpose

This Regulation Impact Statement (RIS) sets out and analyses options for reform to the regulation of certain stock and pet food products currently regulated as veterinary chemical products. The RIS follows the Australian Government Guide to Regulation by:

- describing the problem this reform is seeking to address and establishing why action is needed
- identifying policy options that would address the problem
- determining the net benefit of reform options
- describing who was consulted on the options, how they were consulted and setting out the issues raised in consultation
- picking the best option from those identified
- setting out the process for implementation and evaluation of the preferred option.

The regulation guide requires that the proposed policy options include a non-regulatory option and the status quo.

Section 2: Background

2.1 Regulation of agricultural and veterinary chemical products

Pesticides and veterinary medicines are often dangerous poisons. Their misuse can result in adverse effects to human, animal and plant health, the environment or to Australia's trade. It is important that any potential risks of the use or misuse of agvet chemicals are managed appropriately so that these products do not harm human, animal or plant health, the environment or trade.

Responsibility for the management of the risks of using agricultural chemicals and veterinary medicines (agvet chemicals) is shared between the Australian Government (responsible for control of imports, exports, manufacturing and supply) and the states and territories (responsible for control of the use of these chemicals). This partnership is described in an inter-governmental agreement for the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS).

Responsibility for managing risks of agvet chemical use outside of the NRS regulatory framework also lies with the manufacturers, suppliers and users of these products. The existing regulatory frameworks for consumer protection, public health and food safety along with common law operate at the same time as the regulatory controls of the NRS.

The Australian Government's responsibilities under the NRS are met by the Australian Pesticides and Veterinary Medicines Authority (APVMA), a Commonwealth statutory authority. The APVMA administers the schedule to the *Agricultural and Veterinary Chemicals Code Act 1994* (the Agvet Code) and related legislation. The focus of the Agvet Code is the protection of human, animal and plant health, the environment and trade from the risks of using agvet chemicals.

2.1.1 Agvet chemical registration

Under the Agvet Code, most agvet chemicals must be registered by the APVMA before they may be supplied. Supply of unregistered agvet chemical products is an offence. The use of unregistered agvet chemicals is an offence under most states' and territories' control of use laws.

There are about 11 000 agvet chemical products registered by the APVMA, of which almost 3 400 are VCPs. The remainder are agricultural chemical products (mainly pesticides).

There is an exception for supply or use of a veterinary chemical product (VCP) at the direction of veterinary surgeons. Under state law, veterinarians have the right to prescribe the use of a product contrary to its label, or to allow the use of an unregistered product[1].

To register a product the APVMA evaluates information provided by an applicant for a pre-market assessment. The information must demonstrate the use of the product, in accordance with its label:

- does not pose an unacceptable risk to human or animal health and the environment
- will be effective
- will not unduly prejudice Australia's international trade.

2.1.2 Other regulatory controls on agvet chemical products

Apart from product registration, the Agvet Code allows for less onerous regulation of some products with lower risk profiles. Three other regulatory controls exist:

(i) Exclusion (where products are declared in the regulations not to be a VCP)—risks are controlled by limiting the exclusion to products of known, defined risk and by conditions on the exclusion.

(ii) Reservation and (iii) listed registration—risks are controlled by requiring that products conform to a prescribed standard. (Listed products require APVMA confirm that the product does conform to the standard.) The standard for a reserved chemical product or a listed product addresses the risks that would otherwise need to be considered by the APVMA for each individual product.

The different regulatory controls on different agvet chemicals impose different regulatory burdens on prospective importers, manufacturers and suppliers of these chemicals. The regulatory burden is greater on products that require a product-specific risk management approach. Products that do not require an individual pre-market assessment by the APVMA incur lower regulatory costs. As the risk profile of a product increases, so does the need for product specific risk management (see Figure 1).

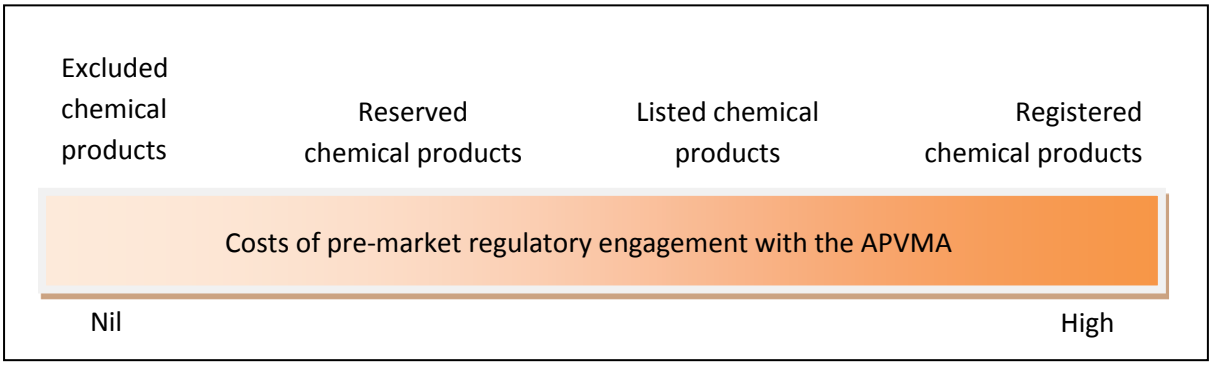


Figure 1 Regulatory controls provided by the Agvet Code

[1] The laws about the prescribing authority of veterinary surgeons vary between states and territories and across species of animals. For example, most states and territories limit the actions of a veterinary surgeon in relation to food producing species but not pets.

A number of products for animals are excluded chemical products (they have been declared not to be VCPs). There are no reserved VCPs, and a single class of VCPs are listed chemical products (joint health products for dogs and horses). The APVMA and industry have so far found that various practical issues restrict the development of suitable standards that would allow for greater reliance on the reserved or listed chemical approach to groups of VCPs. These include:

- restriction in brand delineation through standardised labelling
- restriction in innovation through conformance with narrow standard
- lengthy and repetitious development and consultation processes, noting the breadth of products/uses to be covered in the listed standard
- high APVMA resource needs (time and expertise) in the development process.

These issues are addressed in later reforms to agvet chemicals regulation. Practically, if a product is not explicitly excluded then it must be registered.

2.2 Stock foods

Stock foods are in their simplest guise foods consumed by animals. Only some stock foods are VCPs. Not all stock food VCPs would be subject of the reform described in this RIS.

The term 'stock food' is used for foods for a range of animal species and food product types (from hay, which is not a VCP, through to enhanced feed conversion products that may be VCPs). The term is not usually applied to animal foods for companion animal (pets). For this RIS, as a simplification, the term stock food includes foods for both meat and fibre producing livestock and non-livestock species (for example pets, working animals, show animals and equestrian sports).

2.2.1 Stock foods that are veterinary chemical products

A VCP is defined under Section 5 of the Agvet Code to be any product that is represented or used to:

- prevent, diagnose, cure or alleviate a disease, condition or infestation by a pest in an animal
- cure or alleviate an injury of the animal
- modify the physiology of the animal to alter its natural development or make it more manageable.

VCPs may also be declared in the regulations to be, or not to be, a VCP.

Stock food VCPs (including dietary or therapeutic pet foods, growth promotants, probiotics and vitamin and mineral supplements) make up about 20 per cent of all VCPs. Details about regulated stockfeed VCPs, including uses and the therapeutic or physiological claims of the products, are recorded the APVMA Public Chemical Registration Information System. This is accessible at https://portal.apvma.gov.au/web/guest/pubcris.

2.2.2 Stock foods that are not veterinary chemical products

Not all stock foods meet the definition of a VCP. Products solely intended to sustain life (that is, they are just food for animals) do not require APVMA registration prior to supply in the market. The reform discussed in this RIS does not change the regulation of these sustenance products. They are out of the scope of this reform.

Some stock foods that would otherwise meet the definition of a VCP have been declared not to be VCPs as they do not pose a risk to safety, efficacy or trade such that they require registration. Currently, these are:

- products containing only substances specified in the Veterinary Chemical Products (Excluded Stockfood Non-active Constituents) Order (the SNAC Order)
- products that are medicated stock feeds containing registered VCPs that are used as set out on the label for that VCP, unless it is supplied as a medicated block or lick
- products that are blocks, licks, premixes or supplements containing vitamins, minerals or amino acids at normal nutritional levels to supplement diets.

2.2.3 Risks of stock food use

The APVMA's evaluation of an application for agvet chemical product registration identifies the potential risks from the use of the product. Once registered, the product is subject to risk mitigation strategies to reduce these risks to acceptable (but not necessarily zero) levels.

The magnitude of the risks associated with a specific VCP is highly dependent on the intended use of the product. For example, an obesity product for pets has a very low risk of residues in human food; while a cattle feed delivering antibiotics would have a higher risk of residues in the food chain.

The particular risks of VCP use can include:

- chemical residues finding their way into meat products and entering the human food chain
- chemical residues present in exported meat products at levels not permitted in overseas markets
- harm to humans or the environment through chemical exposure from storage, transport, handling or use
- harm to animals from unintended effects and adverse reactions
- persistence of harm to individual animals where a product fails, especially where it hampers efforts to control and manage outbreaks of disease.

Accordingly, the APVMA's assessment of applications for VCP registration examines four major issues:

- Ingredients
  - the suitability of the product's constituents and the overall formulation of the product
  - the quality of the constituents of the product
- the source of some constituents
- Claims
  - the scientific validity of the claims to be included on the product label[2]
- Manufacturing
  - production of the product under a quality assurance scheme
- Labelling
  - instructions and information to allow the product to be used and handled safely

Table 1 articulates some risks, likelihood and consequence across the spectrum of stock food products

[2] It is an offence to make claims or representations about a registered VCP that are inconsistent with the approved label of the VCP.

2.3 International practice in stock food regulation

Comparable international markets (for example the European Union, New Zealand or the United States of America) approach the regulation of VCPs generally in a similar manner to Australia. However the regulation of some stock foods differs to the Australian approach. Commonly, the international approach is to exclude certain stock food products from the need for pre-market assessment. This is allowed where a stock food conforms to publicly available standards for ingredients, labelling and claims.

Section 3: Problem definition

The regulatory burden imposed on manufacturers, suppliers and users of certain stock and pet foods is not proportional to the risk of using these products. The regulatory costs imposed are not warranted and do not result in risk management outcomes that could be achieved by a less costly regulatory approach. This unnecessarily imposes high costs on industry, limits or delays product innovation and delays the introduction domestically of products available overseas.

3.1 Costs of regulation

Stock food VCPs make up about a fifth of the number of all VCPs. These products recorded sales of approximately $139.5 million in FY2012–13, accounting for approximately 15 per cent of total VCP sales. The Stock Feed Manufacturers' Council of Australia (SFMCA) has estimated that 11.5 to 12 million tonnes of feed for livestock are used in Australia each year[3]. This figure includes all stock feed VCPs as well as stock feeds that aren't products regulated by the APVMA.

The APVMA is one of a number of Australian Government regulators funded by fees and levies imposed on the industry it regulates. The APVMA collects an upfront VCP registration application fee of 40 per cent of the cost of processing the application[4]. The APVMA recovers the remainder of its costs through a levy (tiered between 0.3 - 0.8 per cent) paid by registrants based on the wholesale value of VCP sales and a renewal fee ($450) to maintain a VCP registration. The fee and the levy are payable by the product registration holder annually for the duration of the registration.

The generation of information (including scientific research) to support an application is a costly and lengthy exercise for an applicant. The cost for an innovative product can be between $10 000 and $100 000, depending on the complexity of the trials conducted. Costs may also be incurred when applicants must address specific concerns about residues in exported produce. The information generation process also increases the time it takes to bring new VCPs to market.

VCPs are required to be produced by APVMA-licensed manufacturers (equivalent standards for overseas manufacturers are also accepted). Manufacturers incur costs in developing and implementing manufacturing systems compliant with obligatory manufacturing principles and in the conduct of audits for compliance with those principles. These costs are passed through to the holder of the registration and ultimately the end user of the VCP. The APVMA currently licences around 110 manufacturers of stock food VCPs.

[3] http://www.sfmca.com.au/info_centre/facts_and_figures/

[4] Stock food product application fees ranged from $600 to $2 800 in FY2008–09 to FY2013–14.

The costs of the ongoing monitoring compliance with the VCP regulatory framework is spread across the NRS partners. The APVMA has responsibility for registered product quality and supply up to the point of retail sale. State and territory governments are responsible for the safe use of products and the compliance of meat products treated with VCPs with food standards. The expenditure of the states and territories in monitoring stock food compliance (either as a VCP, or as an animal food more generally) is not expected to change under the reforms described in this RIS[5].

Where the risks of some stock food VCP are not of a kind that requires management consistent with the current regulatory impost described above, the regulatory costs are an unnecessary burden on the payers.

The time taken by the APVMA in completing assessment, including the preparation of information by the applicant prior to seeking APVMA assessment, delays a product's entry to the Australian market. This can result in overseas markets having access to the most innovative products (either new ways of using existing ingredients, or new ingredients) before Australia. This disadvantage is compounded where the pace of innovation in the stock food industry can result in replacement products (with improved performance) entering international markets before the first product is introduced in Australia.

The costs of regulation have impacts beyond a simple increase in cost of stock food VCPs to end users and of reduced profitability and employment in stock food VCP industry. These issues have flow on effects for users who miss out on greater access to innovative and improved products. The stock food industry (including pet and stock food manufacturers) has confirmed these challenges in consultation. The Feed Ingredients and Additive Association of Australia[6] (FIAAA) has estimated that the additional productivity improvement foregone by Australian producers from these delays amounts to a loss of about $10 per tonne of feed annually (noting approximately 11 million tonnes of feed is consumed each year).

APVMA resources currently utilised for assessing stock food CVP registration applications could also be more effectively expended in managing the risks of other agvet chemicals.

[5] No breakdown of specific expenditure by compliance agencies in monitoring stock foods was available. The tasks form part of the wider compliance and monitoring functions of agencies.

[6] Correspondence February 2014.

Table 1 Risks, likelihood and consequences associated with a sample of stock foods that are VCPs

Product type	Risk	Likelihood	Consequence (cattle, sheep, poultry etc)	Consequence (pet)	Consequence (consumers)
Dietary supplement	Over exposure	Possible through poor manufacturing control or over application	Mass animal death, financial loss	Single animal death, expense of veterinary intervention	Distress from harm to animal Decreased productivity may increase costs of produce
	Under exposure	Possible through poor manufacturing control or under application	Developmental issues related to nutritional deficiency (e.g. grass tetany), financial loss, productivity decrease	Developmental issues related to nutritional deficiency, expense of veterinary intervention	Distress from harm to animal. Decreased productivity may increase costs of produce
Growth promoter	Inefficacy	Unlikely, but possible through poor manufacturing control	'Normal' development, no productivity increase	'Normal' development	No improvement in productivity that may have lead to reduction in costs of produce
Antibiotic	Residue in meat	Possible through over application	Antimicrobial resistance and loss of trade markets	Nil	Human exposure
	Antimicrobial resistance	Possible through use of human antibiotics in mass medication for animals	Lack of viable antibiotics	Nil	Lack of viable antibiotics

3.2 Risks being managed

The existing regulatory approach to stock food VCPs (pre-market assessment for registration and ongoing monitoring of compliance) has successfully managed risks of using these products to animal welfare, human health and the environment. There have been less than five significant incidents of residues from animal feeds in meat products exceeding allowable limits in the last decade (identified through routine residue testing of produce). These incidents have been the result of the use of unregistered chemical products, the misuse of registered chemical product or the contamination of feed at the time of manufacture or use (for example, with lead based paint in animal enclosures).

Greater understanding about the risks of manufacturing and using animal nutritional and digestive products has developed through the evaluation of products by the APVMA, overseas regulator practice, scientific publications, successful user practice, and successful practices of the stock food supply chain. Greater understanding about these risks shows that the existing regulatory framework has failed to keep pace with developments in the stock and pet food industries.

In the early 1990s VCPs were primarily based on identifiable chemical active constituents, such as antibiotics or hormones. The mode of action of these products was clearly chemical in nature and the risks they presented were more suited to pre-market assessment. In the years since, the stock and pet food industries have developed feed products that change or supplement an animal's nutritional or digestive processes. Their therapeutic, preventative or developmental effect is achieved through a physiological, rather than traditional chemical, mode of action.

Many stock foods and pet foods now caught by the VCP definition have a more easily defined and mitigated risk profile, due to their ingredients and intended use patterns. However, the current regulatory approach does not differentiate between these types of VCPs and those with more complicated risks (like antibiotics or vaccines) which do require product specific risk assessment and mitigation strategies. The lower risk nutritional and digestive products present is demonstrated in practice by the low number of adverse experience reports received by the APVMA about these products (< 1% of received reports in 2013, < 1.5% of received in 2012)[7]. And also by a lack of demand for monitoring programmes for stock food quality and suitability or for widespread audits of stock food use practices from Commonwealth, state or territory regulators.

However, while certain stock foods might have a well defined and low risk, that risk is not zero. Complete deregulation (that is, the removal of all controls on foods for animals) is not likely to lead to effective management of the risks of using these products. Stock foods enter the human food chain and are used to address sometimes significant animal health and welfare issues. The protection of the food chain and the welfare of animals are areas of community concern warranting the imposition of an appropriate and proportional regulatory burden.

[7] The annual reports of the APVMA Adverse Experience Reporting Program are available at http://apvma.gov.au/node/10946. The annual reports are collated based on active constituent rather than use (stock food). The relevant reports are taken as those including those active constituents routinely included in animal feeds.

3.3 Who is paying?

The regulatory costs for associated with stock foods are experienced by the holder of registration (originally the applicant) and the manufacturer of the product (noting they may be the same entity). The types of enterprises involved in stock foods in Australia spans small to medium enterprises manufacturing specific animal feeds for a small (possibly singular) customer base, through to enterprises operating in multiple international markets (and consequently across multiple regulatory regimes). The costs of regulation (both initial and ongoing compliance) are passed on in the price to users of the products.

Section 4: Options and analysis

The policy goals of this reform are to:

- better align the regulatory effort and burden associated with stock foods with risks posed by these products and their use
- deliver on the government's commitment to reducing unnecessary red tape and supporting Australian producers
- deliver on the government's commitment to adopt appropriate international standards and improve Australia's alignment with international practice for similar products
- ensure Australian farmers have access to safe products to improve their competitiveness
- provide pet owners access to newer, safer animal health care products.

The options considered to achieve these goals are described below. In brief they are:

A. to maintain the status quo requirement for pre-market assessment and registration of all stock food VCPs (status quo)
B. to amend subordinate legislation to exclude some stock food products from the definition of a VCP where the product meets a number of defined conditions (self-determined conditional exclusion—see (i) at 2.1.2 above)
C. to regulate certain stock food products as listed chemical products rather than requiring 'full' registration (listed registration—see (iii) at 2.1.2 above).

The deregulatory benefits of Options B and C relative to Option A (the status quo) have been calculated by the Australian Bureau of Agricultural and Resource Economics and Sciences (ABARES). Full details are outlined in Annex A (with a worked example for Option B provided). All calculations used the Australian Government's regulatory burden measure (RBM) methodology.

4.1 Option A — Status quo

This option would retain the existing regulatory arrangements described in Section 2. As a result, the existing regulatory costs above would persist.

4.1.1 Likely economic impact

Industry submissions have confirmed that the rate of new products being registered would remain consistent with the historical norm under the status quo.

The status quo will not affect the existing levels of competition in the animal feed market.

4.1.2 Timeframe

There is no delay in implementation.

4.1.3 International alignment

The status quo, requiring evaluation of a stock food product by the regulator for veterinary chemical products, does not align with the practices of the European Union, New Zealand, or the United States of America. In these markets equivalent stock food products may be supplied without the need for individual product assessment.

4.1.4 Analysis

Table 2 summarises the risk mitigation approach of the status quo option.

Table 2 Analysis of status quo approach

Factor	Assessment
Risks to human health	Controlled through evaluation of specific individual product's ingredients and workplace health and safety factors.
Risks to animal welfare	Controlled through evaluation of specific individual product's ingredients, claims and manufacture process.
Risks to international trade	Controlled through evaluation of specific individual product's ingredients.
Regulatory effort (industry)	High, requiring detailed technical applications, often including the generation of some primary data to support this.
Regulatory effort (government)	High, requiring assessments of detailed technical applications of each specific individual product.
Ability for innovation	Low; inhibited by the time and costs of registration. Expected to continue to be restricted to the historical rate.
Actions required of industry	Unchanged. Manufacturers will still be required to: achieve and maintain an APVMA manufacturing licence; generate robust scientific evidence specific to product, prepare an application including application fee, submit for APVMA assessment, respond to APVMA queries, release to market, report on wholesale sales value, pay annual renewal fee and levy on sales. Suppliers will still be required only registered VCP stock food, users will be required to only use registered VCP stock foods.
Effect on competition	Unchanged
Alignment with international practice for stock foods	Low, Australia would continue to have significantly higher regulatory burden for certain VCP stock feeds than our trading competitors.
Monitoring and enforcement	Unchanged, responsibility will continue to be: APVMA (supply), states and territories (use), consumer law (adverse effects), food standards authorities (residues), and biosecurity (importation).

Factor	Assessment
Responsiveness to stakeholder expectations/needs	Low

4.2 Option B—Conditional exclusion

As described at 2.1.2, the Agvet Code allows regulations to be made excluding specific classes of VCPs from the definition of a VCP. Excluded products do not require pre-market assessment, registration or renewal of registration.

The description of the exclusion in the regulations allows for the exclusion to be done conditionally. A product would be excluded if it falls within a class of products that meet certain conditions. This is currently done for some stock food products that would otherwise be VCPs, including products containing only substances specified in a legislative instrument (the SNAC Order) and VCPs that are dietary supplements containing vitamins or minerals at normal nutritional levels. These examples, like most products excluded from the VCP definition, are conditionally excluded stock food VCPs.

The product manufacturer or supplier determines for themselves if their product is an excluded product based on whether the product meets the conditions of exclusion. No pre-market assessment by the APVMA is required for excluded products.

This option proposes to exclude a class of stock food products from the VCP definition where products in the class satisfy each of five conditions. These conditions describe a class of products with a well defined risk profile that is adequately managed by maintaining compliance with the conditions. The conditions are:
(i) the product is only for voluntary oral consumption by animals
(ii) about claims (what the product is supposed to do)
(iii) about quality and standards of manufacture
(iv) about product labelling
(v) about ingredients.

A stock food VCP that does not meet these five conditions is not an excluded VCP and will require a pre-market assessment and registration before it may be imported, manufactured, supplied or used. A stock food product in the market that is not registered but complies with the five conditions may be lawfully imported, manufactured, supplied and used. Importers, suppliers and manufacturers of the product are to satisfy themselves about whether the stock food meets the five conditions. The APVMA would enforce compliance with the requirement to supply either registered stock food VCPs or stock food products that meet the conditions of the exclusion through its ongoing monitoring of products in the marketplace and its compliance enforcement strategy.

4.2.1 The five conditions:

Only voluntary oral consumption

Risks to animal safety are often directly related to the method used to introduce substances for consumption by the animal. Some methods of introducing a VCP to an animal (such as intraruminal bolus, by

syringe or stomach tubing) require a level of animal husbandry skill that is not generally present within the wider community and may give rise to animal welfare concerns.

To comply with this exclusion condition the whole product must be voluntarily consumed by the animal, either as a feed or when added to the animals' feed. VCPs to be introduced forcibly to the digestive tract of an animal would not meet the condition.

Claims

To meet this condition, the label for the product (and any accompanying material) must not claim to alleviate or prevent an animal disease or modify the physiology of an animal unless the claim is able to be substantiated by robust scientific evidence. The product supplier will, if requested by a government regulator or a court, need to be able to produce the evidence it relied on to satisfying itself that the claims can be substantiated.

In addition, any product claiming to cure an animal disease can meet the claims condition only if it is supplied solely on the instruction of a veterinarian for the treatment of an animal under his or her care. The Agvet Code currently provides for veterinarians to have access to appropriate products (registered or not) to treat animals under their care, in accordance with state and territory laws applying to veterinarians.

Manufacture

To comply with this exclusion condition, the product must be manufactured according to the requirements of one of a list of quality assurance schemes. This condition manages risks about the quality of manufactured product and about manufacturing systems and processes. Schemes include:

- APVMA manufacturer licensing (according to the APVMA principles of good manufacturing practice)
- feed manufacture standards from the United States of America or European Union (or member state)
- specific domestic feed industry codes of practice.

The ability to include domestic industry codes of practice was identified from consultation with the Australian stock feed and supplier industries and incorporated in the final option.

Labelling

To comply with this exclusion condition, the product label will need to include some specified information, such as information on the safe use of the product and about the ingredients of the product. This will ensure that people who deal with the product (for example, by using it or transporting it) can make informed decisions about that product.

The label condition would also incorporate information identified by stakeholders that would simplify the label (such as ingredient groupings) and means of accessing information (like utilising quick reference codes for a product that does not require batch specific details).

Ingredients

To comply with this exclusion condition, all ingredients in a product must be on at least one of a number of prescribed lists of substances (international or domestic) that are appropriate for inclusion in animal feeds or human food. In addition, the exclusion would provide that inclusion of some specific ingredients in stock

food mean that the product will be a VCP, regardless of whether the ingredient is on one of these prescribed lists.

The international ingredient lists are prepared by international jurisdictions with a comparable approach to risk and who have a strong presence in global trade of produce. These lists of suitable ingredients are routinely used by international manufacturers and suppliers. Where these prescribed lists include a quality standard for an ingredient (such as about minimum purity) this will be a requirement for that ingredient. If a domestic quality standard exists, this will apply. If not, then the most conservative international standard applies.

The use of international standards arose in stakeholder consultation. This identified opportunities to expand the scope, and subsequent benefit, of the reform by leveraging off decisions of suitable overseas jurisdictions. This is consistent with recent government announcements on the greater adoption of international standards as a mechanism for reducing domestic regulatory burden.

4.2.2 Financial impact

The department estimates that 55 per cent (around 190) of currently registered stock food VCPs are likely to meet the conditions of the stock feed exclusion. For these products, and the new products that would enter the market in the absence of a regulatory burden (estimated to be 120 over five years), the deregulatory benefit is calculated under the RBM to be $7.85 million. The assumptions in this calculation are:

- the costs associated with data generation and evaluation will be foregone
- the costs associated with maintaining APVMA GMP licences will be foregone
- the costs associated with completion of government forms and compliance with requirements will be foregone
- consequently an increase number of products will enter the market above and beyond the historical norm.

Details of calculations are included Annex A. Although not included in the RBM calculation an additional $815 000 may be saved by industry through the absence of APVMA fees and levies[8].

The reduced regulatory burden (absence of data generation for registration or licensing manufacturing) allows greater opportunity for new businesses to participate in the stock food market. This accessibility is highly relevant to small enterprises where regulatory burdens often pose a disproportionately large barrier.

Consultation with supplier and manufacturing pet and stock food industry (including specific questions as part of consultation on the draft RIS) identified no likely adverse competition effects. One submission from the user industry stated the lower costs of animal feed production will provide opportunities for smaller stock food manufacturers to enter the market.

Existing registered products that meet the five exclusion conditions would be able to cancel their registrations (avoiding the APVMAs ongoing levy on sales and the need for annual renewal, as well as the associated administrative costs). New products entering the market are expected to increase competition with a potential, but not assured, positive impact on prices experienced by the consumer.

[8] This value, and the corresponding cost to industry, is included for more complete consideration of the overall cost and benefits of this option.

APVMA would experience a reduction in revenue (from application fees, levies, annual renewal fees of approximately $815 000). This will be offset by the reduction in expenses as APVMA would no longer need to assess registration applications or continue the administrative effort associated with maintaining the registrations of affected products. The APVMA, as a cost recovered agency, has established mechanisms to ensure it continues to recover costs for its regulatory operations.

It is estimated that the department has incurred $40 000 in development costs to date.

4.2.3 Other impacts

The expected financial impacts on consumers, industry and the regulator are set out above and describe that the reform is expected to result in equivalent product risk with reduced regulatory effort, reduced costs for product suppliers and consumers and increased innovation. Additional impacts include:

- Consumer confidence and trade—although this option will have equivalent risk management outcomes to the status quo, there is potential for consumers (domestic or international) to not fully comprehend the approach. This could lead to unfounded claims (such as through the media, or by trading partners) that the public is being exposed to greater risks, particularly to food safety. Information made available by the government, regulators and industry should mitigate this impact.
- Supplier responsibilities—the option requires suppliers of products to understand their responsibility to self-assess against the conditions necessary to qualify for exclusion from being a VCP. In practice, market forces may require some primary suppliers to the Australian market to make information available that can be relied on by the subsequent supply chain (such as small business retailers) to be assured that products are validly excluded from being VCPs. These primary suppliers would usually be the parties that would otherwise have had to be the holder of registration, and any such information would be significantly less than would have been needed to support a registration.
- Veterinarian responsibilities—one of the requirements of the claims condition is that, for certain claims (such as curing a disease), only those products labelled for supply on the instruction of a veterinarian meet the exclusion condition. This is consistent with the existing powers a veterinarian has to use their professional judgement to prescribe unregistered VCPs to treat their patients. Nothing will force a veterinarian to prescribe a product.
- Access to products labelled for supply only on the instruction of a veterinarian—some product users may be concerned that they will need to go to a veterinarian to access certain products, with associated time and expense impacts. It is possible that an existing, generally available registered product could have a claim about curing a disease or condition. Deregistering the product (to exploit the deregulatory benefits available under this option) would require that the supply of the product go from generally available to supply only at the instruction of a veterinarian. While a theoretical possibility, consultation with industry has confirmed that all existing registered products of this type are routinely supplied only on the instruction of a veterinarian. In practice no additional impost will be experienced by product users in accessing these products.
- Ensuring compliance—the shift to self-assessment by product suppliers about their compliance with exclusion conditions instead of requiring registration will eliminate APVMA pre-market involvement in the control of supply of these products. Stock food products that don't comply with the exclusion conditions would be unregistered VCPs. As is the case with all other agvet chemicals, responsibility for ensuring that only registered VCPs are supplied remains with the APVMA. The existing compliance arrangements for use of animal feeds (that are the responsibility of the states and territories) remain

untouched and would apply to excluded stock food VCPs as they currently do to registered stock food VCPs.

- State and territory responsibilities – Submissions received from Department of Agriculture and Food Western Australia and New South Wales Department of Primary Industry indicated concerns over increasing the responsibility of state and territory governments in the regulation of these stock food products. In particular that an increased cost of compliance and monitoring might be expected. Under the option proposed, the enforcement and monitoring burden for state and territory governments would remain equivalent to current arrangements. The proposed change means that excluded products previously considered VCPs would be enforced and monitored as animal feeds. Importantly, state and territory governments are responsible (either in full or in part) for the enforcement and monitoring of both VCPs and animal feeds. The change would not increase monitoring and compliance for jurisdictions but simply require a shift in efforts from VCPs to animal feeds.
- The FIAAA and Pet Food Ingredients Association Australia (PFIAA) have estimated that the proposed reform would result in the introduction to the market of a backlog of 120 (100 stock feeds and 20 pet foods over a period of time) products that are currently not viable to register. The SFMCA provided statements on the beneficial impacts for innovative product market entry to stock food manufacturers. Australian Pork Limited, Australian Chicken Meat Federation and Australian Dairy Industry Council and Dairy Australia stated the potential for benefit to producers of access to innovative products in addition to the benefit of reduced costs of existing products.
- International access to Australian market – the reduction in regulatory costs and burdens from the removal of the need for individual product assessment will benefit both domestic and international manufacturers. The strict requirements of Australia's biosecurity arrangements means many products are domestically manufactured product (thus avoiding many of the biosecurity risks) rather than import material. It is expected that this advantage for domestic manufacturers would continue.
- High value vs. low value stock foods – it is expected that for high value stock food products removing regulatory costs will encourage new entrants to the market. The effect on competition of these new high value products will be limited on the basis that high value products are able to absorb the existing costs of being considered VCP. Low value (or niche) stock foods are expected to experience an increase in competition (as the burden of market entry is reduced). These niche products are likely to generate the greatest degree of innovation as stock foods are tailored to specific customer's requirements. As above this approach is expected to benefit local manufacturers more than importers (through the increased costs of biosecurity and transport).

4.2.4 Timeframe

The timeframe for implementation is estimated to be within the first quarter of 2015.

4.2.5 International alignment

This option adopts a similar approach to equivalent stock foods as that of the European Union, New Zealand, and the United States of America; in that stock food products may be supplied and used without the need for individual product assessment where the product is consistent with a set of conditions. Determining conformance with the conditions (for ingredients, labelling, claims and manufacture) is initially the responsibility of the manufacturer or supplier.

This option would also accept the determinations from European Union, New Zealand, and the United States of America for appropriate ingredients for stock food products. The quality assurance programs operating for stock food products in the European Union and the United States of America would be recognised as delivering equivalent levels of protection as Australian protocols.

4.2.6 Analysis

The reform would not affect all stock food VCPs. The reform aims to respond only to those stock food products where risks are well understood and can be effectively mitigated through a standardised approach. This option therefore does not assume that stock foods are inherently low risk or that they are necessarily lower risk than other VCPs. Rather, the risks of some stock food are similar and well defined across a range of products.

The exclusion conditions about claims, labelling, ingredients and quality of manufacture are already familiar concepts in the current regulatory system for stock food manufacturers and holders of product registrations. The design of the five conditions for exclusion ensures that stock food risks, for this class of stock food VCPs, are managed in an equivalent way to that done by the APVMA's individual assessment for product registration (the status quo, Option A). However, the regulatory burden would be much lower.

Some ingredients present risks that do warrant specific individual assessment of a product (such as hormones) or are currently under restriction in stock feeds (vertebrate animal material for consumption by ruminants). The exclusion conditions ensure that such products would not be eligible for exclusion from being VCPs.

Non-compliance (either deliberate or inadvertent) with the exclusion would, in general, constitute a risk to safety. This risk exists to the same extent as under the status quo (Option A).

Table 3 summarises the analysis of this option.

Table 3 Analysis of conditional exclusion option

Factor	Assessment
Risks to human health	Controlled through restriction of ingredients to substances suitable for stock food as well as conditions on manufacturing quality and health and safety labelling.
Risks to animal welfare	Controlled through restriction of ingredients to substances suitable for stock food, restrictions of claims as well as conditions about manufacturing quality and directions for use labelling.
Risks to Australia's trade	Controlled through restriction of ingredients to substances suitable for stock food, minimum quality standards reflecting international practice or domestic need and directions for use labelling.
Risks to the environment	Controlled through restriction of ingredients to substances suitable for stock food and conditions about manufacturing quality and labelling.
Regulatory effort (industry)	Low ($7.85 million deregulatory benefit); the effort to comply with exemption conditions will be significantly less than what would otherwise have been required to support an APVMA registration application.

Factor	Assessment
Regulatory effort (government)	Low; the APVMA would no longer need to undertake assessments of registration applications for these products, and post market compliance mechanisms are already operated by the Commonwealth and state and territory governments.
Ability for innovation	High; the time and resources saved in not having to seek APVMA registration will free industries to bring new products to market with lower cost and delay. Product market entry expected to exceed the historical rate.
Actions required of industry	Reduced. Manufacturers required to participate in an appropriate manufacturing quality assurance scheme, establish that ingredients conditions are met, identify or generate substantiating information for claims, meet label conditions. Suppliers may stock products consistent with the exclusion conditions. Users may use the product consistent with the state and territory controls on feeds for sustenance of an animal and food quality controls.
Effect on competition	Increased availability of new products and introduction of new manufacturers. Reduction in prices for stock food products and ingredients.
Alignment with international practice for stock foods	High
Monitoring and enforcement	APVMA (supply consistent with exclusion conditions), states and territories (animal feed, use), consumer law (adverse effects), food standards authorities (residues), biosecurity (importation).
Responsiveness to stakeholder expectations/needs	High

4.3 Option C—Listed registration

This option would regulate certain stock food products by classifying them, under the existing mechanism, as listed chemical products. This option would provide a lower regulatory burden regulation pathway than registration as while listed chemical products must be registered. As described at 2.1.2 above, listed chemical products must conform to an APVMA prescribed standard that, if complied with, addresses the risks of using the prescribed class of chemical products.

The standard provides a common risk mitigation strategy for all the products in the class. The APVMA, rather than the product supplier under the conditional exclusion option (Option B—see 4.2 above), would determine if a product is consistent with the standard through a pre-market assessment. This evaluation will require an application and information from the prospective holder (at a financial and time cost).

The processes for standard creation, assessment and control of listed chemical products are established within the Agvet Code. The responsibility for development of standards rests with the APVMA. The APVMA could, but could not be obligated to, prescribe the exclusion conditions described for Option B above in the standard. For the purposes of analysis the department has assumed that no additional controls other than

the exclusion conditions described for Option B would be proposed in an APVMA listed chemical product standard.

4.3.1 Timeframe

The timeframe for implementation has been estimated at 6–24 months depending upon resource allocation within APVMA (noting that APVMA is currently completing implementation of a wider three-year reform agenda) and consultation process (necessary as part of standard creation, additional to that already conducted).

4.3.2 International alignment

As for Option B, this option would adopt the international determinations for appropriate ingredients for stock foods and quality assurance schemes. However the need for evaluation of individual products to establish conformance with the standard would continue. This would be a substantial reduced burden from the status quo, but remain higher burden than experienced for equivalent products in the European Union, New Zealand or the United States of America.

4.3.2 Analysis

While the regulatory burden imposed for listed registration is less than for an unlisted registered chemical product, it remains higher than the conditional exclusion approach in Option B. Option C retains APVMA's role pre-market assessment of these products ensures products will be accurately matched with an individually appropriate risk management strategy. The actual risk management prescription for the product, however, will likely be equivalent to that achieved through the status quo (registration) or Option B.

The estimated deregulatory benefit of Option C is $6.72 million. An additional $58 000 is estimated to be saved in APVMA fees. The key assumptions of this option (as differing from Option B) are:

- the costs for licensing manufacturing facilities with the APVMA would be foregone
- the growth in new products will be less than for Option B (estimated at 108 products or 90 per cent of the Option B result), recognising some products will not enter the market where any level of pre-market assessment exists.

Regulatory costs are reduced primarily through lower costs of assessing and providing information to demonstrate that a product conforms to the defined standard. These savings would be delayed until APVMA develops the required standards to implement the listing option. It is estimated that the APVMA's costs would exceed $100 000 in the development of the listed standard and subsequent legislative implementation. The APVMA would experience a slight reduction in application costs (about $58 000) but would retain the revenue from levies and annual renewals[9].

Table 4 summarises the analysis of this option.

The impacts to suppliers and manufacturers are similar to those for Option B (assuming any listing standard largely reflect the Option B exclusion conditions). However, the continuing need for APVMA pre-market assessment (although less intense than needed for registration) retains some of the barriers to innovation

[9] These values are not included in the calculation of regulatory costs, but are included here for completeness.

that exist under the status quo. The effect on competition is therefore expected to be the same as for self-determination with an estimate of 10 per cent less growth in new products. Similar to Option B, industry submissions have identified no adverse affects likely to arise from an increase in competition.

The monitoring and enforcement of this option would be identical to those of the status quo, as listed chemical products are effectively the same as registered chemical products. The efforts of the states and territories and the APVMA would not be affected.

Table 4 Analysis of listed chemical product

Factor	Assessment
Risks to human health	Controlled through restriction of ingredients to substances suitable for stock food as well as conditions on manufacturing quality and health and safety labelling.
Risks to animal welfare	Controlled through restriction of ingredients to substances suitable for stock food, restrictions of claims as well as conditions about manufacturing quality and directions for use labelling.
Risks to Australia's trade	Controlled through restriction of ingredients to substances suitable for stock food, minimum quality standards reflecting international practice or domestic need and directions for use labelling.
Risks to the environment	Controlled through restriction of ingredients to substances suitable for stock food and conditions about manufacturing quality and labelling.
Regulatory effort (industry)	Medium ($6.72 million deregulatory benefit); the effort to submit applications and have them assessed by the APVMA would be significantly less than currently required.
Regulatory effort (government)	Medium, the APVMA would be required to assess applications for conformance with the standard, with supply of product prohibited without registration.
Ability for innovation	Medium; primarily innovative means of combining existing ingredients. Introduction of new products expected to exceed the historical rate.
Actions required of industry	Reduced. Manufacturers required to participate in an appropriate manufacturing quality assurance scheme, establish that ingredients conditions are met, identify or generate substantiating information for claims, meet label conditions. Suppliers unchanged, may supply only registered or listed stock food VCPs. Users may use registered or listed chemical stock food products as currently.
Effect on competition	Increase presence of new products and new manufacturers. Some reduction in prices for stock food products and ingredients.
Alignment with international practice for stock foods	Medium
Monitoring and enforcement	APVMA (supply), states and territories (use), consumer law (adverse effects), food standards authorities (residues), biosecurity (importation).
Responsiveness to stakeholder expectations/needs	Medium

The costs of ongoing registration of the product (application fees, renewal fees and levy) will continue to be incurred by the industry, as part of the APVMA cost recovery activities. The costs for maintaining an APVMA manufacturing licence will not necessarily be incurred, although a standard may require demonstration of quality assurance practices.

Some segments of industry believe[10] there is great value in the continued involvement of government in the pre-market assessment of stock food products. Primarily these stakeholders cited needs for strong reassurance for protection of animal welfare. The consensus opinion of industry, at the completion of the consultation process, was that the 'listed chemical product' approach involved a level of regulation that, while lower than currently experienced, remained excessive relative to the risks of the product in the specific circumstances of the reform. A number of suppliers and manufacturers[11] also stated that any degree of pre-market assessment would impose restrictions on chemical access not experienced for similar products in competitive markets internationally.

Only submissions from Department of Agriculture and Food Western Australia and New South Wales Department of Primary Industry indicated any level of support for this option over Option B.

Section 5: Analysis summary

The reform described in this RIS aims to reduce the regulatory burden on those stock food products where the risk aspects are well understood and can be effectively mitigated through a standardised approach. This RIS identifies three options for consideration. Each option has been assessed for its ability to address the problem of a regulation imposing costs disproportionate to the risks imposed by the use of some stock food products, as discussed in Section 3.

The consultation stages for this reform have identified areas for potential improvement of the status quo. These are discussed in detail in Section 6, but have (where adopted) been included in the options' analysis above. The costs and impacts presented were identified through consultation with:

- users, manufactures and suppliers
- veterinary health care professionals
- the APVMA and ABARES.

Table 5 summarises the options against the policy objective of aligning regulatory effort with risk and other potential benefits of reform.

Table 6 summarises the deregulatory benefit for all options.

In considering options the deregulatory benefits to industry (linked to the regulatory burden imposed under each option) was balanced against the risk posed by use of these products and each option's ability to manage the risk. While Option C (the listed chemical product option) represents a significant improvement from the status quo in aligning regulatory burden with product risk, Option B offers the greatest deregulatory benefit while managing risk to acceptable levels.

[10] Industry round table, and subsequent discussions with department February – May 2014

[11] Industry discussions with department over development of options

The existing compliance arrangements for use of animal feeds (that are the responsibility of the states and territories) remain untouched and would apply to excluded stock food VCPs as they currently do to registered stock food VCPs

Section 6: Consultation process

Reform to the regulation of stock foods and pet foods as veterinary chemical products will have a direct impact on a variety of stakeholders; from importers, manufacturers and suppliers of products, to users and pet owners and consumers of meat animals fed these products. Government (across the Commonwealth and states and territories) has an interest in all points of the supply chain and is also a major stakeholder in the process.

6.1 Previous consultation

Targeted and open consultation has been conducted to develop and refine reform options. Engagement with stakeholders on potential for reforms to stock feeds has been ongoing since November 2013. Participants in the consultation provided input on successive iterations of reform options, each iteration being informed by the feedback received on the previous version.

Stakeholders were invited to attend a workshop in February 2014 hosted by the department to collaboratively discuss the reform principles and the broad approaches being considered. Initial consultation established as consensus amongst manufacturers and suppliers that the status quo was undesirable and explored both Option B and C. The department has also had detailed discussions with particular stakeholders. The participants in the targeted consultation are detailed in Annex B.

The majority of stakeholders in the development phases considered Option B to represent the best outcome. Option C was explored and discounted by stakeholders as requiring further refinement as it was slower to be delivered, more complex and imposed greater costs than Option B.

Some states have expressed concern through consultation regarding the potential for poor quality stock foods to be supplied. Mechanisms addressing these concerns and which deliver the current levels of risk control are included in Options B and C.

A draft RIS was released on 7 October 2014 for public consultation incorporating the comments and discussion from the initial consultation. This was distributed both through the department's website and through direct email to likely interested animal industry and community stakeholders. All reform options were open for comment over the 30 day public consultation period. Specific questions of interest in the development of the final RIS are detailed in Annex C.

6.2 Outcomes of consultation

Stakeholders raised specific issues across all phases of consultation they and the department's response, are detailed in Annex D. The options analysed in this RIS reflect the consideration of all stakeholder comment, including those received on the draft RIS released for consultation. All refinements to either Option B or Option C were to improve their delivery on the policy goals. The department received 14 submissions on the draft RIS.

Table 5 Summary of option analysis

	Status quo	**Self-determination**	**Listed chemical product**
Change in risk profile	Nil change	Mitigated change in risk profile	Mitigated change in risk profile
Alignment of effort with burden	Low	High	Medium
Alignment with international practice	Low	High	Medium
Supports increased rate entry of new products to market	Nil	Yes	Yes
Time frame for implementation	Immediate	Immediate on decision	6-24 months of decision
Deregulatory Benefits (millions)	Nil change	$7.85	$6.72
Recognition of industry standards and quality procedures	Nil	High	Moderate

Table 6 Summary of compliance cost for all options

Average Annual Regulatory Costs (from business as usual)				
	Change in costs ($ million)			
	Business	**Community organisations**	**Individuals**	**Total**
Option 1 (status quo)	$0	$0	$0	$0
Option 2 (conditional exclusion)	-$7.85	$0	$0	-$7.85
Option 3 (listed registration)	-$6.72	$0	$0	-$6.72
Are all new costs offset? ☐ yes, costs are offset ☐ no, costs are not offset ☑ deregulatory, no offsets required				
Total (change in costs—cost offset) ($million) - $7.85				

6.2.1 Comments on the preferred option

The preferred option of the majority of submissions was Option B (71 per cent). Submissions (6) from the manufacturing industries stated support for Option B, either as presented or with minimal amendments. Some select comments from stakeholders are set out below:

"We concur with the estimates of costs in Annex A."

"We believe the nature of the risks, industry standards and the 5 deregulation conditions more than adequately address risk."

"We believe the discussion and assessment of risk and non-compliance in the RIS accurately reflect the position under Option B."

"The industry welcomes the sensible, risk-based approach presented in the legislative Exposure Draft and outlined in Option B in the RIS: Legislative reform – self-determination of Veterinary Chemical Product Basis. This option reduces unnecessary regulatory burden, while appropriately managing risks. "

"It could be argued that as a self-assessment system, companies could market a product that does not meet the four specific criteria and thus present a performance risk to the users purchasing these products. Nutritional stockfood [sic] products are however low risk and any less than expected performance will be reflected in the product and its long term sales. We see this as a commercial issue that should be outside regulatory control."

"Risks such as the presence of contaminants we see as equally applying under the existing APVMA controls and the preferred option. Holding APVMA registration does not guarantee that products are not manufactured and sold that potentially contain contaminants. We do not see the preferred option as presenting any greater risk than presently exists."

Submissions (4) from user groups stated supported for Option B. Select comments:

"As a major export industry, it is particularly important to the dairy industry that trade risks are considered. These appear to be appropriately managed through criteria for suitability and quality of ingredients."

"Option B...pragmatically balances risk management with regulatory burden."

"Access to new, safe and efficacious ingredients for feed will improve the health of Australia's pig herd, potentially reducing reliance on antibiotics..."

6.2.2 Comments on other options

Submissions (2) from state government bodies stated support for Option A, with possibility of Option C being considered as a compromise position pending further collaborative development.

"In reforming the regulation of stock food products, the Department of Agriculture must ensure that their preferred option (i.e. self-determination) delivers the same or better safe feed assurances when compared to existing legislative requirements. The arguments put forward in the Regulations Impact Statement do not adequately address DAFWA's concerns regarding the potential to increase biosecurity, food safety or trade risks....DAFWA was not included in any consultations for Option C."

"DAFWA maintains concern that veterinarians (and others) will be permitted to make claims consistent with section 5(2) of the Agvet Code without regulation or active compliance by the APVMA. It is DAFWA's opinion that this move will undermine the standing of the Agvet Code."

"The RIS makes much of the jurisdictions' capacity to control the use of veterinary chemical however does not acknowledge that the move [self-determination]....revokes any legislative capacity the jurisdiction may have to control the use of stock feeds in food producing animals."

"DAFWA has explicitly stated in previous correspondence that it would not undertake monitoring activities for those stock foods excluded from APVMA registration."

Submissions (2) from community groups stated support for options other than those presented or made no specific comment on preferred options.

"However for specialised dog or cat food for animals with compromised health or life threatening conditions, registration is needed as their dietary needs are complex and form part of a treatment plan, along with specific veterinary medical treatments."

"...as veterinarians are very busy and will only research 1 or maybe 2 such specialised diet products and not all that are on the market. New entrants to the market will not be able to establish themselves as busy vets will stay with the products they know work and not take the time to investigate others or try them due to the risk of pet deaths."

"This legislation should not be changed until a similar system of recalls and adverse experience reporting is set up by the APVMA and widely publicized so pet and livestock owners know where to go if they think they have a problem."

6.3 RIS status

The only major decision point for this reform is the implementation, or not, of Option B. This decision, expected December 2014 to January 2015, will be informed by this RIS.

The announcement by the Minister for Agriculture, the Hon Barnaby Joyce MP, in September 2013 of his intention to reform stock feed regulation was informed by preliminary costing by ABARES and the consultation with stakeholders from November 2013 until September 2014.

Section 7: Preferred option

The preferred option is for the Option B reform, excluding certain stock foods and pet foods from pre-market assessment and registration contingent on certain conditions. This option:

- addresses stakeholders'(industry and government) expectations to reduce regulation
- simplifies regulation
- better aligns regulatory effort for manufacturers and government with risks posed by the product
- reduces regulatory benefit for industry ($7.85 million)
- has a short timeframe for delivery
- improves market access to new products
- delivers equivalent protections to the health of humans, animals and the environment, and to Australian trade as the status quo.

By removing the time and cost required for registration, it is anticipated that the preferred reform will better facilitate access to innovative stock foods that increases the productivity of Australian farmers and promote health of Australian animals.

The burden of ongoing monitoring and compliance of excluded products is a relevant consideration in all deregulatory measures. The variety of existing monitoring and regulatory systems in addition to pre-market assessment of products by the APVMA, and the ability for compliance failure under existing arrangements were relevant. Regulatory systems addressing food standards, consumer law, civil legal action, exporting requirements and importing controls in destination countries operate independent of the Agvet Code currently and would continue to provide adequate control over the life of these products.

Section 8: Implementation and Review

8.1 Implementation

The implementation of the preferred option, subject to the Minister for Agriculture's agreement, will be in two key stages.

Refinement and finalisation of draft regulations and supporting documents

The final RIS and draft regulations will be provided for Ministerial approval before consideration by the Federal Executive Council.

Commencement of regulations

The commencement of the preferred option for reform is intended, at earliest, for February 2015. The final date will be communicated through public release on government websites. The primary risk to this stage is a delay arising in the preceding stage.

8.2 Review

The performance of preferred option (if implemented) can be evaluated through a range of factors:

Reduction in regulatory burden and improved efficiency

This reform was initiated by the needs of users and stock food manufacturing industries. Feedback for these stakeholders on effectiveness of the reform in reducing red tape will act as a primary subjective measure of the successful implementation.

The APVMA's efficiency in assessments of registration applications for other VCPs is expected to improve as resources previously expended on stock food products are redirected. The performance indicators are reported through APVMA's Annual Report, and would act as an objective measure of the reform.

Improved innovation and diversity in the market

The presence of innovative products or an increased variety of current products in the market place, will act as indicator of success of the reform. Both reflect an improved ease of market access. This may be measured through feedback from stock food users on whether a decrease in stock foods available internationally but not domestically has occurred.

Surveys in future years to identify the number of new products introduced to Australia would also act as a measure of success, with the base being an average of 20 new products registered per year[12].

Understanding of self-determination

The effective understanding of self-determination and appropriate and accurate application of the aspects is measure of success of the reform.

Avenues exist for suppliers and manufacturers to seek, of their own volition, specific APVMA advice in relation to a product. The APVMA, for a fee, may provide technical assessments prior to an application being made, though it need never actually be made.

[12] 120 products registered since 2008.

In future years, the use of APVMA educational and assistance tools (technical assessments and self-help decision trees) to validate a supplier's determination about the compliance of a specific product with the exclusion conditions will act as a measure for the understanding of reform. Reduction in usage over time would indicate an increased understanding by industry.

Ongoing compliance

The degree of non-compliance (measured in instances and volume of product) will act as a measure of the success of the reform. A decline of non-compliant (inadvertent or deliberate) product in the marketplace will be reflective of effective implementation and education of manufacturers and suppliers. This approach will be largely subjective in the absence of a baseline (other than anecdotal) for the effectiveness of current regulatory arrangements to restrict entry and supply of unregistered products.

Annex A - Calculating the reduction in regulatory burden from the stock foods reform

Three options for reforming the regulation of stock food have been proposed. ABARES has calculated the change in regulatory burden and benefit for all options.

Stock food products are considered to have four primary areas of Australian Government regulatory costs, with each option having a different level of effect:

- registration with the APVMA
- payment of annual fee
- payment of annual levy
- certification of manufacturing facility under the Good Manufacturing Practice (GMP) standards.

It has been assumed, following discussions with industry, that 100 per cent of manufacturers would choose to utilise a quality assurance system other certified under Good Manufacturing Practice by the APVMA.

To quantify any reduction, ABARES calculated three types of costs:

- compliance cost of registering new products
- delay cost of registering new products
- compliance cost of ongoing requirements (annual fee, levy and GMP certification)

These were calculated as per the Regulatory Burden Measurement (RBM) framework with data provided by the department, APVMA and industry representative bodies FIAAA and the PFIAA.

Number of products impacted

Only some products in the stock food market currently regulated as veterinary chemical products would be subject to the reforms discussed in this RIS. To determine the proportion of products affected, a random sample of products (42 of 383 registered VCPs) was obtained and their respective ingredient lists reviewed. Only the ingredient aspect was reviewed, as all other aspects (labelling, manufacture and claims the other primary areas discussed in this RIS as a basis for deregulation) are effectively addressed through registration and the associated pre-market assessment.

The department found 55 per cent of sampled products contained only ingredients present on one or more of the international lists of ingredients considered as appropriate for inclusion in stock foods. This proportion was used to calculate the number of products impacted by the reform.

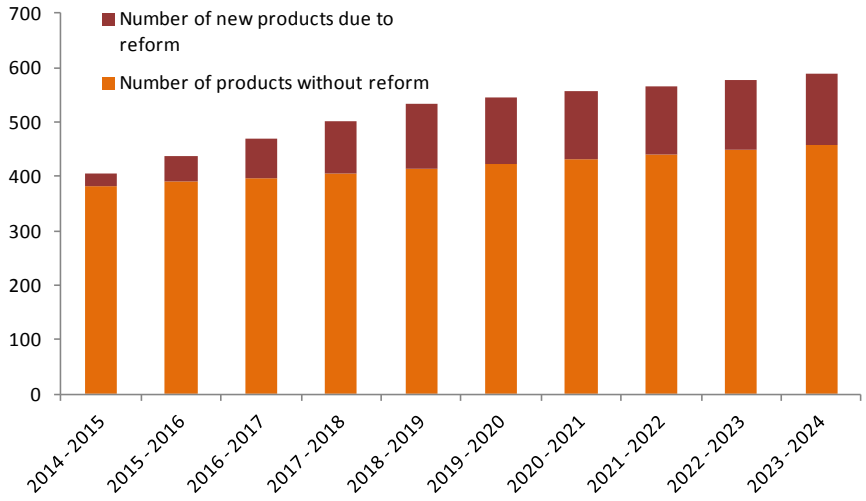
The number of products in the stock food market is growing. ABARES assumed that this trend would continue over the ten year horizon (Figure 2). The ten year average was used for costing.

The current regulations act as a barrier to entry for stock food products. Discussions with the FIAAA and PFIAA indicate that the proposed reforms would result in the release of a backlog of 120 (100 stock feeds and 20 pet foods) products that are currently unviable to register. It was assumed:

- the backlog of products would be released over the first five years

- this new market segment would grow at the same rate as the existing market once the backlog was released.

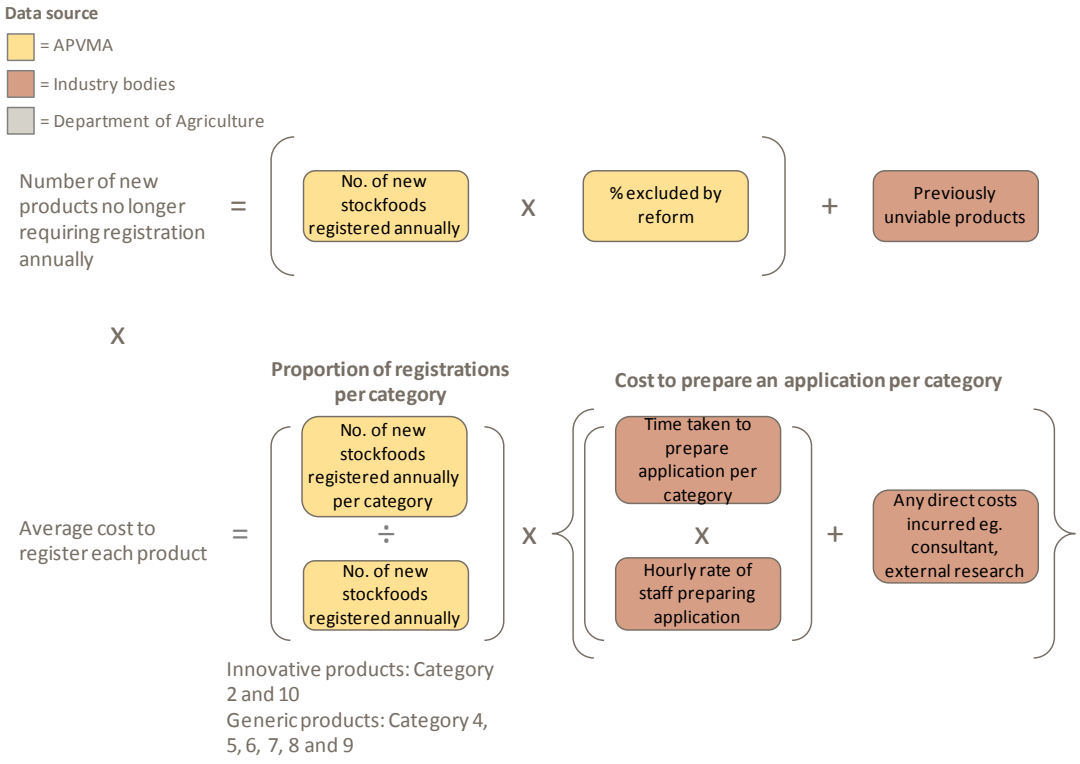
Figure 2 Number of stock food products over the next 10 years



Compliance cost of registering new products

The reduction in compliance costs of registering new products was a simple multiplication of the number of products and the cost of registering a product (Figure 3). Reference to category 9 is present for completeness of calculations, but no applications have been received by the APVMA across the sample window.

Figure 3 Methodology used to calculate the compliance cost of registering new products



The complexity entered into the calculation via the differences in stock food products in two ways.

Firstly, the testing and supporting documentation required to register a pet food is substantially more than for a stockfeed because of the greater number of active ingredients. Secondly, the APVMA has two different processes for registration depending on whether the product is innovative or generic. Innovative products contain active ingredients not yet registered in Australia while generic products use only currently registered active ingredients. The process for generic products is simplified, and with a lower burden of information, than the innovative process.

The FIAAA and PFIAA provided average costs for registering innovative (novel ingredient) products. The estimates comprised registration preparation, consultant fees, research trials and dossiers to support applications. Industry bodies surveyed their members to determine the average cost of preparing an application to register an innovative pet food and stock feed. The average costs used were:

- $200 000 for innovative stock foods
- $350 000 for innovative pet foods
- generic products were assumed to cost 5 per cent of the above values. Costs are reduced are because of the ability to rely on previously assessed information.

Delay cost of registering new products

The methodology used to calculate the reduction in delay costs of registering new products is outlined in Figure 4. The approach was taken from the Victorian Regulatory Change Measurement Manual. The calculation relies heavily on business' commercially sensitive information which they are highly hesitant to share. To obtain the required information, ABARES worked directly with two pet food companies and two stock food companies. The industry bodies and the department were not involved in the process due to the sensitivity of the information.

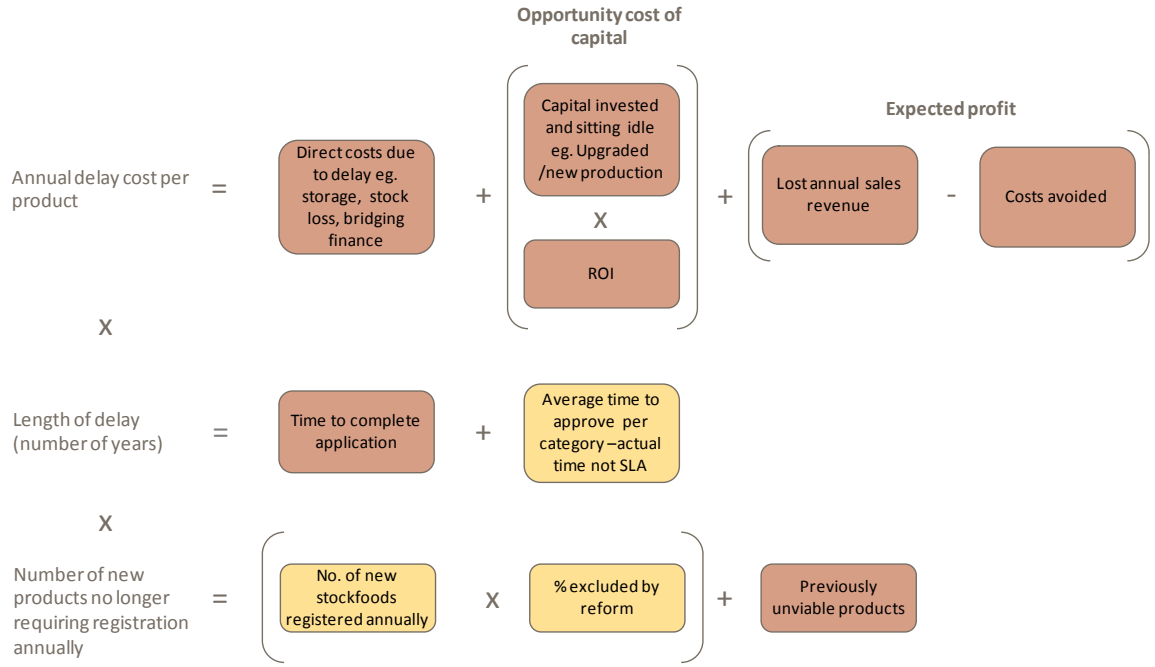
After speaking with businesses in the stock food industry, the calculation was significantly simplified due to the realities of the production methods used. For instance, it was determined that these businesses do not incur any costs or invest any capital before approval of the new product is granted by the APVMA. Furthermore, when approval is granted there is already sufficient capacity in production lines and supply chains to handle the new product without further investment. As an example, one business said that their production occurs offshore and the addition of the Australian market would only result in a 1-2 per cent increase in production. Therefore there is no opportunity cost of capital.

As a result, the annual delay cost per product was determined as the expected annual sales revenue for new products multiplied by the business' target EBITDA (earnings before interest, taxes, depreciation and amortisation). This is a measure of the expected annual profit foregone due to a delay of one year.

To determine the actual cost imposed by the delay, the value calculated as per the above was multiplied by the average length of delay. To determine its value, the preferred approach is the critical path method. It takes into consideration tasks that can be performed in parallel resulting in a more accurate estimate.

The APVMA has statutory timeframes for the length of time it takes to determine the approval of new stock foods. These timeframes represent maximum allowed assessment time (and in the past did not include the time where requirements for additional information were made of the applicant), leaving stock food businesses facing uncertainty on the exact date of a decision. As such, stock food businesses do not prepare to release a product until its approval is granted. This means the whole approval delay is included in the delay cost. Part of the application delay is also included but only the part that would not occur as a business as usual process. An example of a task not included in the application delay is the length of time to complete residue tests that ensure the product is safe. This is a task that any responsible business would perform irrespective of whether they have to register a new stock food or not.

Figure 4 Methodology used to calculate the delay cost of registering new products

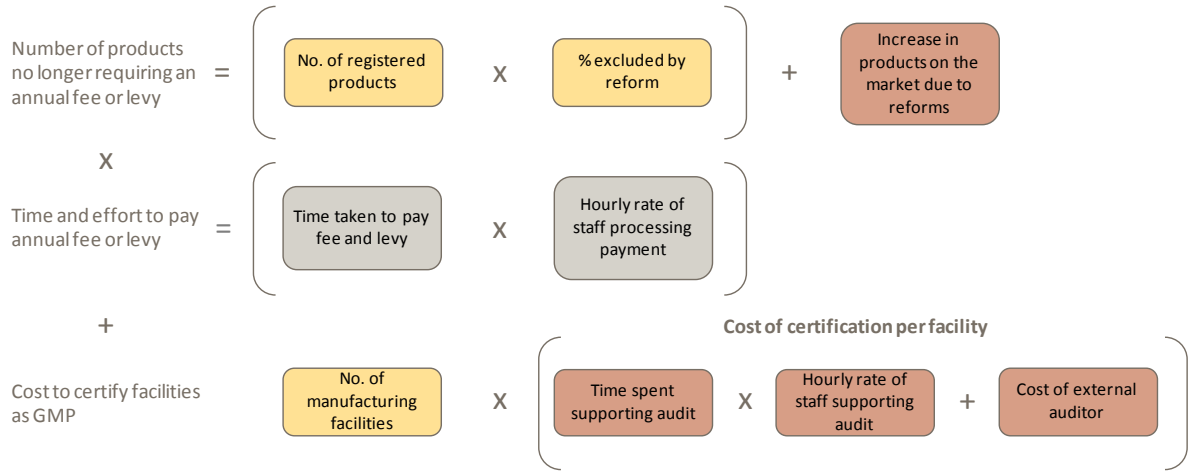


Compliance cost of ongoing regulatory requirements

The reduction in compliance costs imposed by ongoing requirements (payment of annual fee and levy, and GMP certification) was a simple calculation (Figure 5). The compliance cost of paying the annual fee and levy was determined as the product of staff time, wage rate and number of products.

To maintain GMP certification businesses are required to have their manufacturing facilities audited to ensure they meet approved standards. Businesses incur two costs as part of this process, staff time and consultant/auditor fees. The audits occur every two to three years depending on the risk profile of the facility. A frequency of two and a half years was assumed for the calculation.

Figure 5 Methodology used to calculate the compliance cost of ongoing regulatory requirements



Annex B – Stakeholders involved in consultation

Those marked with * have been involved in targeted consultation over the course of reform development.

Stakeholder/ Entity	Role	Submission on draft RIS
ACCORD	Peak Body	
Advanced Veterinary Therapeutics	Community	√
Animal Health Australia	Peak Body	
Animal Medicines Australia*	Peak Body	√
Australian Chicken Meat Federation	User	√
Australian Companion Animal Council	Peak Body	
Australian Dairy Industry (including Dairy Industry Council and Dairy Australia)	Peak Body	√
Australian Egg Corporation Limited	Peak Body	
Australian Lot Feeders Association	Peak Body	
Australian Pork Limited*	User	√
Australian Veterinary Association	Peak Body	√
Bioproton Pty Ltd	Industry	√
Cattle Council of Australia	Peak Body	
Dairy Australia	Peak Body	√
Feed Ingredients and Additives Association of Australia*	Peak Body	√
Goat Veterinary Consultancies	Community	√
Inghams Enterprises Pty Limited*	User	
International Animal Health Products	Industry	√
Meat and Livestock Australia	Peak Body	
National Farmers Federation	Peak Body	
Pet food Ingredients Association of Australia*	Peak Body	√
Pet Industry Association of Australia	Peak Body	
Ridley Agriproducts	User	
Rivalea*	User	
Sheep Meat Council	Peak Body	
Stock feed Manufacturers' Council of Australia*	Peak Body	√
Veterinary Manufacturers and Distributors Association	Peak Body	
Australian Pesticides and Veterinary Medicines Authority*	Govt	

Stakeholder/ Entity	Role	Submission on draft RIS
Chief Veterinary Officer - Australia	Govt	
Department of Agriculture *	Govt	
State and Territory governments (ACT)*	Govt	
State and Territory governments (NSW)*	Govt	√
State and Territory governments (NT)*	Govt	
State and Territory governments (QLD)*	Govt	
State and Territory governments (SA)*	Govt	
State and Territory governments (VIC)*	Govt	
State and Territory governments (WA)*	Govt	√

Annex C – Specific question to stakeholders through the draft RIS consultation

References to @x relate to an exposure draft of possible amending regulations for the Agricultural and Veterinary Chemicals Code Regulations 1995

- Does the RIS accurately reflect the issues surrounding the regulation of stockfeed and pet food that are currently regulated veterinary chemical products?
- Which RIS option do you prefer?
- Will any specific RIS option better encourage new products to enter the Australian market? If yes, how soon would new products be introduced? What effect will the introduction of new products have on the market for stockfeed and pet food products?
- Are the assumptions about regulatory costs (presented in RIS Annex A) accurate?
- Will the preferred option in the RIS improve the balance between regulatory cost and the risks of using stockfeed and pet food products?
- What changes, if any, to the preferred option in the RIS are required?
- What costs, if any, are increased under the preferred option in the RIS? Are these costs reduced more under another option?
- What risks, if any, are increased under the preferred option in the RIS? Are these risks reduced more under another option?
- Considering the criteria for excluded nutritional and digestive products in the draft regulations (see clauses @5 to @8 on pages 7 to 13):
- On ingredients—the preferred option in the RIS does not require that direct fed microbial ingredients of stockfeed and pet food products be treated differently to other kinds of ingredients. Should this be changed so that direct fed microbial ingredients instead require registration? If yes, why? (see clause @5)
- On labelling—should a crude nutrient analysis (describing every ingredient of the product) or a key nutrient analysis (where only ingredients that relate to claims made about the product) be required? Should the analysis be as is required for human foods? (see clause @7(1)(d))
- On manufacturing—are there other quality assurance requirements that could be included that are the equivalent of those already described? (see clause @8)

Annex D – Outcome of issue arising during consultation and development

Area	Industry comment	Outcome	Departmental response
Recognition of Australian (national and state) feed ingredient standards	Where Australian specific risks are identified (e.g. the potential for contaminated ingredients being incorporated into product) an Australian specific control should exist.	Incorporated into Options B & C	Any Australian (national or state and territory) standard to minimise the risk of poor quality (or contaminated) products will apply to ingredients in a deregulated market. In the absence of a domestic standard, the most stringent international quality standard must be applied to that ingredient.
Involvement of veterinarians for specific use patterns and control of supply	Currently the claims for a VCP are rigorously evaluated by the APVMA assessment process during the assessment process, to establish a sound scientific belief in the claimed efficacy of the product. Allowing claims for 'curing' a disease or condition in an animal and potential for adverse animal welfare outcomes.	Incorporated into Options B & C	An equivalent level of rigor to ensure animal welfare for stock food products in a deregulated market with claims of serious consequence (i.e. curing a condition) can be achieved through the professional judgement of veterinarians for animals under their care. This is consistent with existing veterinary prescribing rights13.
Additional listings of appropriate ingredients	The Official Publication of the Association of American Feed Control Officials represents a government endorsed system of ingredients that are routinely utilised in animal feeds. Australia may have needs in animal feeds that differ from those internationally and a process is required to allow ingredients for animal feeds to be domestically determined.	Incorporated into Options B & C	The processes for the Official Publication are similar to those lists of New Zealand and the European Union, and includes those ingredient listed as 'generally recognised as safe' through Code of Federal Regulation in the United States of America. Recognising the needs of domestic industry and the expertise of the APVMA, a mechanism should be included in the deregulated market.

[13] Veterinarians can currently prescribe any unregistered products to treat an animal under their care, provided that they are operating in accordance to requirements of the jurisdiction that they are licence to practice in.

Area	Industry comment	Outcome	Departmental response
Adopting all current APVMA complimentary animal health product	APVMA currently determines a group of products as complimentary animal health products, all ingredients provided here should be included in products for self-determination	Partially incorporated into Options B & C	The APVMA would have the ability to determine ingredients suitable self-determination products. Where a specific list with legislative basis exists this is being adopted. Complementary animal health products have no specific legislative basis outside of VCP.
Unintended impacts of reform	Certain blocks and licks are currently declared not to be VCP, and are excluded from the need for licensed manufacture. Reform to simplify the exclusions will capture these products and potentially subject them to manufacturing quality requirements. This would be an increase in regulatory burden, and should be avoided.	Incorporated into Options B & C	The history of use of block and lick products without incident in the absence of manufacturing controls supports the continuing exception of these products from the manufacturing aspect. The self-determination approach excludes these blocks and licks from the requirement for a recognised manufacturing quality system.
Recognition of relevant industry code of practice and international manufacturing accreditations	The stock food manufacturing industry, independent of any government reform has been developing codes of practice as an alternative for the existing arrangements for manufacturing licences. Recognising the importance of quality assurance to the effective mitigation of a products risk. Allowing certain international manufacturing accreditations to be recognised would also reduces any unnecessary duplication of effort for compliance with multiple and comparable standards.	Incorporated into Options B & C	Where equivalent controls can be achieved independent of government involvement these should be adopted. In this instance the combined controls of the other factors allow a broader approach to manufacturing quality assurance. We note that the codes were developed to ensure the quality and reputation of industry and started from the basis of the existing legislated manufacturing quality control system.
Crude ingredient analysis	Key nutrient analyses including those that relate to any claim are appropriate.	Incorporated into Options B & C	Any reform will require key ingredient analysis to provide information to users.

Area	Industry comment	Outcome	Departmental response
Labelling requirements when relying on international models	While providing for the reliance on international models that define acceptable claims for stock foods (e.g. EU Directive 2009/39 on Foodstuffs for Particular Nutritional uses) the proposed options do not capture the conditions associated with making those claims (as detailed in the same document).	Incorporated into Options B & C	Where a product relies on the international model to support a claim (and mitigate the risk to animal welfare) the conditions of the international model should also apply.
Expiry dates on products	Canned pet food product is routinely supplied only with a date of manufacture but not an expiry date or a statement advising on the shelf life of the product. A requirement for this information will oblige industry to amend its processes.	Incorporated into Options B & C	Expiry dates is an appropriate mechanism for controlling the risk to animals of off food. The need for access to the information is more relevant than its location. The expiry date will e included as information that may accompany the label (i.e. accessible electronically) under the self-determination approach.
Separating antimicrobial from antibiotic ingredients	Some ingredients have antimicrobial action but are not of the type of risk the provision prohibiting antimicrobial substances from the reform is attempting to control.	Incorporated into Options B & C	A more specific definition of antibiotic substances (based on scheduling in ht e Poisons Standard) that would be excluded from deregulated approaches is proposed to ensure eth maximum benefit of the reform while retaining the control of risks.
Defining the term 'treat/treating'	The term 'treat' is used with a spectrum of meanings in the animal food industry, stretching from curing a disease through to preventing or alleviating a condition. Greater clarity on where 'treat' rests will aid industry.	Not incorporated into any option	To define additional terms (beyond those used within the Agvet Code) leads to an approach of having to define all possible terms. It is appropriate to allow a court to interpret the meaning of treat within a claim or representation of a product in both context and through reference to other sources such as the Macquarie Dictionary.

Area	Industry comment	Outcome	Departmental response
Moving 'alleviate/alleviating' to claims only possible with veterinarian involvement	Veterinarians and product users will have less confidence in the safety and efficacy of products claiming to prevent or alleviate disease as there will have been no independent assessment of claims as is currently the case. Increased access to therapeutic feeds for animals may encourage animal owners to self diagnoses and self treat their animals with corresponding impact on animal welfare.	Not incorporated into any option	While the department recognises an increase in owners taking proactive control of animal treatments, this is possible the existing circumstance. Through providing sufficient information on products and robustness approach of a reformed environment the ability for an animal owner to make an informed choice about lower-risk claims is possible. These claims are such that the opportunity for veterinary involvement is retained. Those of curing a condition will require the direct involvement of a veterinarian to ensure the animals welfare.
'Appropriate' instructions for safe handling	Pet food products have at best simplistic directions for safe handling. Without any qualification the requirement for instructions for safe handling may result in perverse details having to be included on a product label and affect the value of any reform.	Not incorporated into any option	Any requirement for instructions for the safe handling of the product is intrinsically to the product. All instructions must be relevant to the product, i.e. appropriate. The need for additional qualification in statute is considered unnecessary.
All information should be included on the label	The listing of all information relevant to the product (including expiry date) should be listed on the label, and not accompany the label (e.g. accessed electronically).	Not incorporated into any option	Noting that some stock feeds are packaged in small single serve containers (e.g. cat food) the ability for the label to contain relevant information and remain legible or proportional to the container are relevant factors to allow some information to accompany the product.

Area	Industry comment	Outcome	Departmental response
Requirement for substantiating information to be easily accessible and in plain English.	A manufacturer is required to have information supporting a product's therapeutic claims. The manufacturers of products recommended by veterinarians are likely to be very proactive in making this information freely available for veterinarians to assess. However, in the current draft of the regulations, there are only minimal safeguards against less reputable operators self-assessing and marketing products direct to consumers with low-level (or no) evidence.	Not incorporated into any option	A consumer utilising a product where access to information has been denied by the supplier is making that choice. Redress pathways exist in the event of adverse experience.
Cascade of manufacturing quality systems	As written the proposed approach of self-determination does not introduce a hierarchy to which manufacturing quality system is preferred over another. This would be desirable. Subsequent comment: Removing flexibility through a cascade would be counter to the goals of reform.	Not incorporated into any option	To introduce this approach would in all practical terms nullify all options other than the pinnacle of the cascade. If APVMA licensing is highest, it would exist and all would need to comply with it regardless of any industry code or international standards. Similarly if an industry code was the primary, international approaches would not be an option, as the industry code would exist.
APVMA GMP to be the only manufacturing quality standard	The risk of poor quality product is increased through quality assurance schemes other than GMP. With licence numbers to be reported on the label.	Not incorporated into any option	Industry codes of practice are reflective of the needs of industry and aware of the demands of their markets, including in the quality of products. Restricting to GMP would not realise the maximum reduction in regulatory burden possible under self-determination.