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

October 2014

Regulatory Impact Statement Status: Interim/Consultation

# Contents

## Glossary of Terms

| | |
|---|---|
| ABARES | Australian Bureau of Agricultural and Resource Economics and Sciences |
| AGGR | Australian Government Guide to Regulation |
| agvet | Agricultural and veterinary |
| 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 |
| PUBCRIS | Public Chemical Registration Information System |
| RBM | Regulatory Burden Measurement |
| RIS | Regulation Impact Statement |
| SNAC Order | Veterinary Chemical Products (Excluded Stockfood Non-active Constituents) Order |
| the department (unless otherwise stated) | Australian Department of Agriculture |
| VCP | Veterinary Chemical Product |

# Section 1: About this regulation impact statement

## Purpose

This Regulation Impact Statement (RIS) sets out an analysis of the need, and options, for reform to the regulation of certain types of stock and pet food as veterinary chemical products.

This RIS follows the Australian Government Guide to Regulation (AGGR) by:

- establishing the problem government is seeking to address
- defining why government action is needed
- identifying a range of policy options that would address the problem
- determining the net benefit of each option
- consolidating the consultation to date and specifying future opportunities for stakeholder input
- deducing the preferred option
- establishing the process for implementation and evaluation of the preferred option.

The AGGR requires that the policy options include a non-regulatory option alongside regulatory approaches and consideration of the status quo.

This RIS is provided, along with draft regulations implementing the reform, to allow stakeholders to consider the assumptions and data underpinning the reform.

## Opportunity to comment on the reform

The Department of Agriculture (the department) is seeking stakeholder views on draft regulations and this RIS, particularly on the following questions:

1. Does the RIS accurately reflect the issues surrounding the regulation of stockfeed and pet food that are currently regulated veterinary chemical products?
2. Which RIS option do you prefer?
3. 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?
4. Are the assumptions about regulatory costs (presented in RIS Annex A) accurate?
5. Will the preferred option in the RIS improve the balance between regulatory cost and the risks of using stockfeed and pet food products?
6. What changes, if any, to the preferred option in the RIS are required?
7. What costs, if any, are increased under the preferred option in the RIS? Are these costs reduced more under another option?
8. What risks, if any, are increased under the preferred option in the RIS? Are these risks reduced more under another option?
9. Considering the criteria for excluded nutritional and digestive products in the draft regulations (see clauses @5 to @8 on pages 7 to 13):

(a) 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)

(b) 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))

(c) On manufacturing—are there other quality assurance requirements that could be included that are the equivalent of those already described? (see clause @8)

All responses (except where confidentiality issues are identified by the author/submitter and accepted by the department) will be made available through the department's website. Personal details other than the authors name and organisation (if any) will not be published. If any information contained in a submission should be treated as confidential, the author should clearly identify the sensitive information and provide reasons for treating it in-confidence.

Submission should be made to agvetreform@agriculture.gov.au.
The department will acknowledge the receipt of all submissions, but will not formally reply to each submission.

The closing date for submissions is 7 November 2014.

# Section 2: Background

For the purposes of the *Agricultural and Veterinary Chemicals Code Act 1994* and related subordinate legislation and this RIS, the term stock food is taken to include foods for livestock and non-livestock species (for example pets, working animals, show animals, equestrian sports).

Specific details of the products, including uses and therapeutic or physiological claims may be accessed through the Australian Pesticides and Veterinary Medicines Authority (APVMA) Public Chemical Registration Information System (PUBCRIS) at www.apvma.gov.au.

## Current regulation of agricultural and veterinary chemical products

The regulation of agricultural chemicals and veterinary medicines (agvet chemicals) is shared between the Australian Government (with responsibility for control of 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).

Other regulatory and legal frameworks, including consumer, public health and common law, operate alongside the supply and use controls of the NRS.

The control of supply aspects of the NRS are administered by the Australian Pesticides and Veterinary Medicines Authority (APVMA), an Australian Government statutory authority. 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.

## Veterinary chemical products and stock food

Under the Agvet Code any product that meets the definition of a veterinary chemical product (VCP) is subject to regulation by the APVMA. A VCP is defined under Section 5 of the Agvet Code as any product that is represented or used to:

prevent, diagnose, cure or alleviate a disease, condition or infestation by a pest in an animal; or

cure or alleviate an injury of the animal; or

modify the physiology of the animal to alter its natural development or make it more manageable.

The definition is intentionally broad, encompassing products intended and claimed to have physical effect on an animal, as well as those used for physical effects independent of their original purpose. This breadth is necessary to reflect the risks posed by these products.

All VCPs require evaluation and registration by the APVMA, prior to supply into the Australian market, as they may pose risks to the safety of humans, animals, the environment or trade. This 'pre-market' evaluation determines the risks of a product and whether the mitigation strategy proposed on the label (instructions for use, safety measures etc) appropriately manage those risks. The purpose of regulatory control in this situation is to ensure the safety of human, animal and environmental health coupled with protecting Australia's international trade.

Risks of VCPs broadly may arise from:

- chemical residue in produce entering the human food chain or impacting Australia's trade
- exposure to either humans or environment from storage, transport, handling or use
- unintended effect on an animal or a lack of intended effect.

The likelihood of any risk is dependent on the nature of the product. For example a product intended only for pet use has a low likelihood of residues in food, while a product applied as a backline drench would have a high exposure likelihood for users.

Similarly the consequences of any event vary with the product, based on the likelihood of an event and the proliferation and exposure to the product. A product for single animal dose might result in the unintended effect of animal death (serious consequence) but would be localised to a single animal. Another product resulting in the unintended effect of hair loss (minor consequence) of animals, where the product is applied to 50 per cent of Australia's cattle herd would be a significant event.

It is the consideration of these risks, understanding of the consequences relative to the likelihood, and proposed mitigation strategy that is the purpose of pre-market assessment of VCPs.

The pre-market assessment considers the risks of the product holistically across four major areas:

- Ingredients, active and non-active constituents
- Claims

- Manufacturing
- Labelling.

Each application for registration and the associated risks are assessed on an individual basis. In practical terms this represents a bespoke assessment of each product. As part of its assessment the APVMA considers the:

- proposed quality of each ingredient
- source active constituents
- use of licenced (or equivalent) manufacturing facilities
- instructions for safe handling and use of the product
- scientific validity of claims or representations on the label about the product.

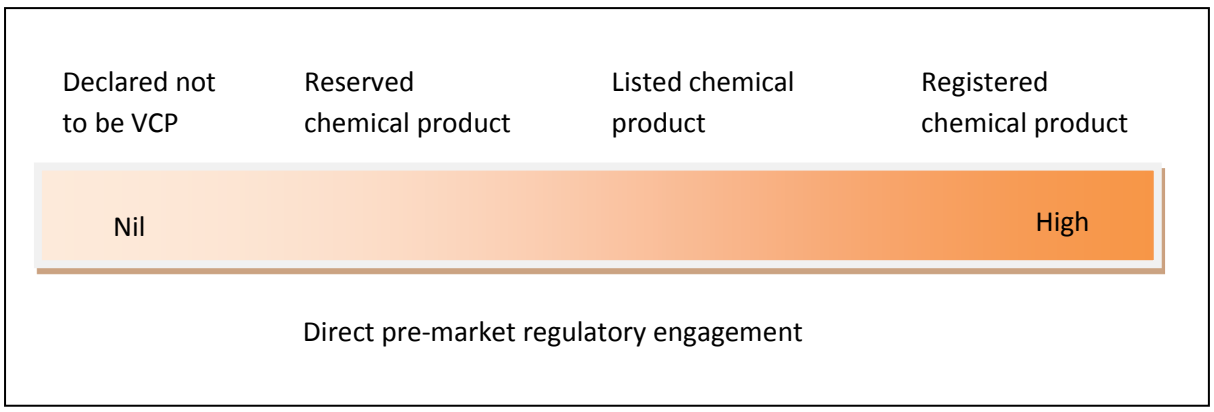
The degree to which each is assessed varies with the level of innovation of the product.

Stock food products that meet the definition of a VCP, that is, those intended to achieve a therapeutic, preventative or developmental effect in an animal, require evaluation and registration by the APVMA prior to lawful supply within Australia.

VCPs may be considered to effectively exist across a spectrum, from those affect an animal development (improve muscle development), through those with benign therapeutic claims (may alleviate itchy skin) and ending with products manufactured, represented, supplied and used to treat the most serious of animal health conditions (vaccines).

The Agvet Code recognises this spectrum through providing four broad categories of regulatory control; exclusion, reservation, listed registration and registration. The regulatory engagement and burden increases (in general terms) across these categories (See Figure 1). The first three categories require specific legislative provision to apply to a class of products, otherwise registration is the only option to allow lawful supply.

**Figure 1 Spectrum of regulatory approaches of the Agvet Code**




The Agricultural and Veterinary Chemicals Code Regulations 1995 (the Code Regulations) declares some products whose primary purpose is not as a therapeutic product to not be a VCP (i.e. exclusion). Any product declared by the Code Regulations not to be a VCP is not subject to

regulatory controls on supply through the Agvet Code, and does not require APVMA's evaluation and registration.

The Code Regulations currently declare that a stock food product is not a VCP if the:

product contains only substances specified in the Veterinary Chemical Products (Excluded Stockfood Non-active Constituents) Order (the SNAC Order)

product is a medicated stock feed containing a veterinary chemical product registered by the APVMA for use in accordance with that registered product label and is labelled as such, unless it is supplied as a medicated block or lick[1]

product is a block, lick, premix or supplement containing vitamins, minerals or amino acids that is at normal nutritional levels to supplement diets.

No veterinary chemical products are currently reserved or listed chemical products. In the development of the legislative framework (1994 onwards) consideration of risk has resulted in a binary approach to regulation (registration or exclusion). At a simplistic level the categories may be considered to reflect the risk of a product, from low risk for excluded products through to high risk at registration. A more accurate description is to view the categories as reflecting the need for individual, or bespoke, mitigation of product risk. The risks of excluded products are effectively controlled through the description of the exclusion.

The risks of reserved and listed products are controlled through conformance with a pre-determined standard, with listed registration requiring government engagement to confirm conformance with the standard. Registration of a product reflects that a unique approach is necessary to address the risks of each product.

To effectively access the lower burden options it is necessary to be able to develop a standard approach that can apply broadly to a class of products, rather than on an individual basis. The standard must address the risks that would otherwise be considered by the APVMA.

Section 3 outlines how some stock food products currently classed as VCPs requiring registration present risks that can be addressed through standard approaches. These products may be subject to a different regulatory approach than other VCPs.

## Process of registration

To register a product the APVMA evaluates data (or scientific argument) presented by applicants to determine that the use of the product, in accordance with its label:

is safe to human and animal health and the environment

would be effective and

will not unduly prejudice trade.

[1] Blocks or licks are blends or mixtures of one or more stock feed ingredients compressed or poured into a solid block form for voluntary consumption by livestock and hence difficult to control the amount ingested by an individual animal.

An application fee to cover part of the APVMA's cost of evaluation for registration is paid by applicants.[2] There are costs to the applicant associated with preparing the application and in responding to requests for clarification from the APVMA.

The generation of data can also be a costly exercise for an applicant. The cost for establishing the effectiveness or safety of an innovative product can be between $10 000 and $100 000, depending on the complexity of the trial conducted. Costs above this may be incurred where the potential for residues in consumable produce must be investigated.

The provision of scientific argument rather than primary research data may reduce such costs. This is most commonly achieved when an applicant can establish that the chemical properties of the proposed product are the same as those of a currently registered product (i.e. data has been previously assessed by the APVMA). This process of establishing chemical similarity could still attract costs of several thousand dollars. Further complications in registration may arise from intellectual property associated with, and limitation on use of, data previously submitted by other parties in support of their products.

Overseas data submitted for evaluation may also require supporting domestic studies. These studies account for any differences in environment or animal husbandry practices between Australia and overseas jurisdictions. They also establish that the product is expected to behave in a similar fashion to that seen internationally.

VCPs are also required to be manufactured in facilities licensed by the APVMA (or to an equivalent standard for overseas manufacturers). A manufacturer is required to conform to production quality principles in order to obtain and maintain their manufacturing license. There are costs associated with the development of processes and site audits by independent bodies. The cost of the former is dependent on both the complexity of the manufacturing process and nature of the product, while the latter may amount to several thousand dollars bi- or triennially. These costs are passed through to the applicant, and ultimately the end user.

The ongoing costs of the wider regulatory scheme is recovered after registration through a levy (0.3 - 0.8 per cent) on the wholesale value of sales of the product and an annual fee ($450) to maintain product registration (i.e. lawful market access). The annual fee and the levy are payable by the product registration holder for the 'life' of the product.

The costs of the ongoing monitoring of stock food, and VCPs more generally, is spread across the NRS partnership. APVMA has responsible for registered product quality and the supply of unregistered chemical products. The state and territory primary industry or agriculture departments are responsible for the safe and appropriate use of a product and the quality of produce resulting from the use.

Supply of VCPs in the absence of registration constitutes a breach of the Agvet Code. The use of unregistered VCPs is constitutes a breach of control of use laws in most states and territories. A

[2] Stockfood product application fees ranged from $600 - $2800, based on fees paid FY2008/09 – FY2013/14

range of response options are available to the relevant enforcement agencies up to criminal prosecution and civil penalty provisions.

A registered chemical product must be supplied in accordance with the particulars recorded for that product in the Register of Chemical Products[3]. These particulars include details on the composition of the product, the quality of the incorporated active constituent and the sites of manufacture. Where the quality of a non-active ingredient is varied the APVMA is notified of the change to determine if any increase in risk occurs and a product recall warranted.

## Stock food and pet food markets

It has been estimated by the Stock Feed Manufacturers' Council of Australia that approximately 11.5 to 12 million tonnes of feed for livestock is used in Australia each year[4]. This figure includes all stock feeds (VCPs and non-VCPs), but does not include pasture grazing, hay, and silage feed.

In 2013 63 percent of Australian households had a pet[5]. The majority of pets are fed with prepared diets rather than 'table scrapping', with an increasing trend in breed specific and age specific foods[6].

Approximately 120 stock food products (for more than 30 holders of registration), have been registered by the APVMA since 2008. These products are distributed through rural supply stores, pet supply stores and retail grocery outlets (in the case of pet foods).

Products registered with the APVMA for 2012–13[7] that fall broadly within the definition of stock food[8] include:

46 antibiotic and anti-infective supplements

132 dietary/therapeutic pet foods

66 digestive enzyme supplements

69 electrolytes

69 growth promotants

23 iron and haemopoietic agents

23 probiotics and prebiotics

14 tonics and stimulants and

236 vitamin, mineral and nutritional supplements.

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[3] PUBCRIS reflects the publicly available (i.e. not confidential) aspects of the Register of Chemical Products.

[4] source

[5] Animal Health Alliance, Pet Ownership in Australia 2013

[6] Petfood Industry Association of Australia, FIAA Technical Seminar 2014, Melbourne.

[7] As detailed under the category nutrition/metabolism for 2013/14, http://archive.apvma.gov.au/publications/gazette/2014/04/gazette_20140225.pdf

[8] It is not expected that all stockfood products currently regulated as VCP are within the scope of this reform.

These products:

- are approximately 20 per cent of all registered VCPs
- have combined product sales of ~ $139.5 millionin 2012–13 (~ 15 per cent of total VCPs product sales)
- list 116 different sites of manufacture.

As discussed earlier the risks, likelihood and consequence associated with a VCP vary with the product. Table 1 articulates some these vectors across the spectrum of stock food products.

Table 1 Risks, likelihood and consequences associated with a sample of stock food VCPs

| **Product type** | **Risk** | **Likelihood** | **Consequence (cattle, sheep, poultry etc)** | **Consequence (pet)** |
|---|---|---|---|---|
| Dietary supplement | Over exposure (certain supplements are toxic at high concentration) | Possible through poor manufacturing control or over application | Mass animal death, financial loss | Single animal death, expense of veterinary intervention |
| | Under exposure | Possible through poor manufacturing control or under application | Developmental issues related to nutritional deficiency (e.g. grass tetnay), financial loss, productivity decrease | Developmental issues related to nutritional deficiency, expense of veterinary intervention |
| Developmental increase | Inefficacy | Unlikely, but possible through poor manufacturing control | 'normal' development, no productivity increase | 'normal' development |
| Antibiotic | Residue in meat | Possible through over application | Human exposure and antimicrobial resistance, loss of trade markets | Nil |

The assessment by the APVMA reduces the likelihood of these risks to acceptable (but not zero) levels, recognising the assessment is on an 'ideal' scenario. A product can always be misused or a manufacturing control by-passed.

A limited number (less than five in a decade) of significant incidents have occurred in relation to animal feeds. These have been the result of the use of unregistered chemical products, misuse of registered chemical product or contamination of feed at time of manufacture or use (lead based paint in animal enclosures). The food standard controls reacted to ensure public safety once the issue was identified, routinely through residue monitoring of produce.

To date no formal quality monitoring program of stock foods, and few broad audits of use practices, are undertaken by the regulators (Commonwealth, state or territory). Compliance resources are allocated proportional to the identified risk, with engagement targeted rather than industry wide.

### International practice

The comparable international markets (when considering approaches to regulation of risk) of the United States of America, European Union and New Zealand approach the regulation of VCPs in a similar manner to Australia. However the regulation of certain stock foods differs to that adopted in Australia. The approach, realised in different fashions in each location, is to exclude from the need of formal assessment certain animal feeds where those feeds conform to standards. These standards include specific ingredients (listed in each country), labelling and claims.

## Section 3: Problem definition

The VCP definition was developed at a time (early 1990s) when chemical products primarily included identifiable chemical active constituents, such as antibiotics or hormones. The mode of action of these products was definitively chemical in nature. In the years since, the stock and pet food industries have developed feed products intended to have therapeutic, preventative or developmental effects without traditional active constituents. These products (consistent with the definition of VCP) operate through changing or supplementing nutritional or digestive processes.

Many stock food products are preventative rather that treatment products. The following are examples of nutritional/digestive stock food products that currently require registration:

vitamin and mineral supplements at or above normal nutritional levels to prevent specific conditions such as tetany, facial eczema and scours

enzyme diets to increase feed conversion within an animal's gut, thus improving the animal's quality

therapeutic diets to alleviate or prevent obesity, urinary tract infections or bladder stones

food additives to reduce stress or anxiety in animals.

Anecdotal information provided by members of both the stock food manufacturing and user industries indicates a range of products that are routinely supplied and used but may be considered within the definition of a VCP, consequently these products may be considered to be unregistered.

Examples include:

zinc oxide supplied as fertiliser for spreading on pasture to address mineral deficiency in an animal's diet leading to facial eczema

dry cat food product with claims for 'increased calcium for maintaining healthy teeth and bones, tuarine for healthy eyesight'.

A broad definition to capture 'risky' products must be coupled with the correct alignment of regulatory approach (registration, listed registration, reservation, exclusion) to risk. The legislative delineation of VCPs across the regulatory spectrum has not kept pace with industry advances.

The potential risks to animal welfare, human safety or the environment of these nutritional/digestive products are different to that of other VCPs (such as vaccines) due to their ingredients and intended use patterns.

The risks of using these nutritional/digestive products are understood and could be adequately mitigated by setting a standard practice of mitigation. As a result, despite these nutritional/digestive products meeting the current definition of a VCP (in that they intend to achieve a therapeutic or physiological change) the degree of regulation (individual pre-market assessment) exceeds that warranted by the products risk.

Greater understanding about the risks of manufacturing and using nutritional/digestive products has developed through:

- historical evaluation of products by APVMA
- overseas regulator practice (see Section 2)
- scientific publications
- user experience, including animal health practitioners and intensive agriculture specialists
- supply chain practices of feed additive suppliers and feed manufacturers.

The understanding of how a class of product behave and how the common risks are controlled allows a standard mitigation strategy (acceptable risk level) as an alternative to registration.

The regulatory failure to be addressed is one of effort for all parties (government and industry) in conforming to the process of regulation compared with the risk being controlled. If a different regulatory approach (with lower effort for all parties) can deliver the equivalent levels of safety for human, animal, environment and trade, the regulatory approach should change.

The stock food industry (including pet and stock food manufacturers) has stated some of the consequences of the existing system of bespoke assessment that act as drivers for reform:

the high cost (initial and ongoing) of meeting regulatory requirements

limitations of the current regulatory system that delay or prevent innovation and the introduction of products available overseas (for example, through costs, data requirements and assessment timeframes)

manufacturing and quality assurance regulatory requirements inappropriate for these products as the requirements are geared towards veterinary pharmaceutical products

difficulties meeting regulatory hurdles that are not relevant to the risks of using the product (for example, demonstrating a 'developmental product' is effective or would not cause harm to exposed animals).

These concerns reflect in part the findings of the Productivity Commission in 2008[9] that unnecessary regulatory burden can:

reduce a firm's profitability and influence production decisions in ways unintended by regulation

create a competitive disadvantage for firms based on size or geographical location

impede the introduction of safe or more effective chemicals

can reduce the net benefit to the community with increasing compliance costs with no offsetting benefit.

The current regulatory approach focussed on individual pre-market assessment is inconsistent with the approach taken in comparable overseas markets for some stock foods (for example, United States of America, New Zealand, and the European Union), placing a restriction in product access for Australian primary producers not experienced by our competitors.

It is important to note that the case for reform is not predicated on the assumption that stock foods are inherently low risk, or that they are lower risk than other VCPs. The risks of some stock foods can be managed in other ways.

Another problem to be addressed is the time and resources devoted to stock food products by the APVMA in assessment and regulation. These resources could better be deployed to the consideration of innovative products addressing more serious conditions or animal health effects, or reviewing older chemistries to confirm continued safety.

Not all stock foods meet the definition of a VCP, such as products solely intended to sustain life. Therefore, these products do not currently require APVMA's evaluation and registration prior to supply in the market. This reform is not intended to change the regulatory burden on these sustenance products.

## Section 4: Options

The policy goals of this reform are to:

[9] *Chemicals and Plastic Regulation*, Productivity Commission, August 2008. http://pc.gov.au/projects/study/chemicals-plastics/docs/report

achieve a greater alignment of 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

ensure Australian farmers have access to safe products to improve their competitiveness

provide pet owners access to innovations in animal health care products.

A complete deregulation (i.e. removal of all regulation to the extent of declaring all foods for animals are not VCPs) is not considered a viable option. Stock foods enter the human food chain and, as indicated above, include claims to address significant animal health issues. It is reasonable to assume when determining viable options to explore in the reform, a community expectation would exist that a level of regulatory control is retained. Any intervention to better align the regulatory effort to the risk of the product must be done in a manner that continues the mitigation of risks to human, animal and environmental health and Australia's trade reputation.

The options considered to achieve these goals are described below.

The option for reservation of nutritional/digestive products was originally considered. In developing the reform options it was recognised that if any reform was necessary it was either that the risk profile was understood to an extent that no direct regulation was warranted or the lightest direct regulation (listed registration [Option C]) was necessary.

## Option A – Status quo – registration as veterinary chemical products

This option retains the existing regulatory requirements described in Section 1.

The timeframe for implementation is immediate.

## Option B – Legislative reform – self-determination of VCP status

This option operates on the premise that for circumstances where the factors of risk can be well defined, a standard approach to risk management is possible; rather than individual product and risk mitigation assessment by the APVMA.

The Code Regulations currently provide for specific classes of products to be declared as not to be VCPs, i.e. they are excluded from the operation of the Agvet Code. Current examples of excluded products encompass both general classes (colour intensifiers for aviary birds) and specific classes (topical product applied to fur to cosmetically alter the animals appearance if there is no antiseptic; no claims are made beyond cosmetic; not supplied or used for therapeutic purposes).

This option proposes to continue this existing approach by amending the Code Regulations to exclude certain stock food products from the definition of a VCP. This exclusion would specify the circumstances for the exclusion through five aspects. This would allow manufacturers and suppliers to self-determine the need for a product's registration.

The aspects are:

that the product is only for oral consumption by animals

satisfies requirements about claims (the described intended purpose for the product)

satisfies requirements about product labelling

satisfies requirements about quality and standards of manufacture

satisfies requirements about ingredients.

The aspects encapsulate a risk profile (see Figure 1) that is well defined, and may be adequately managed through specificity in each aspect and the complimentary controls imposed by other regulatory regimes (as opposed to direct regulatory oversight by the APVMA through pre-market assessment). The other controls include:

complementary state/territory law regulatory systems (e.g. control of use, fair trading etc.)

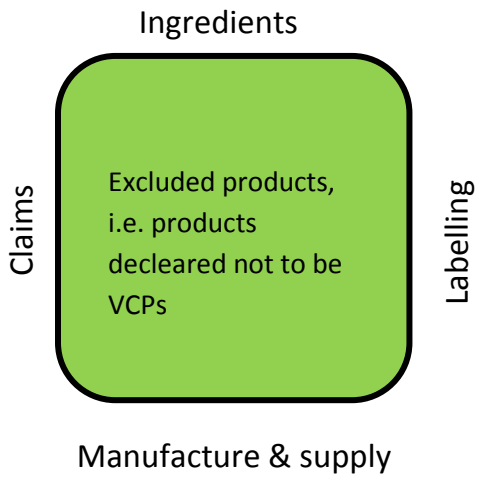
Australian Consumer Law

common law

industry product stewardship

produce quality assurance programs.

**Figure 1 Risk region defined by the acceptable risks of manufacture, labelling, claims and ingredients for a feed consumed by an animal**




While the requirements for claims, labels, manufacture and ingredients would not be assessed by the APVMA on a individual product basis (as products consistent with them would be declared not to be VCP); the requirements provide a transparent boundary identifying acceptable levels of risk and the appropriate mitigation strategy. By operating in unison the requirements maintain, at a minimum, the existing levels of protection for animal, human and environmental health, and risks to Australian trade.

The Code Regulations would provide that only stock food products that meet the above five aspects are declared to not be VCPs. Products containing antibiotics or hormones, or other risks warranting

bespoke consideration (such as not meeting one of the requirements), would continue to require registration as the risks are not controlled.

In the following sections the term 'product' is taken to mean a nutritional/digestive product that would be subject to the reform.

### Claims

The requirement for claims would directly engage a veterinary surgeon's professional judgement in the treatment of animals under their care. This would include the ability to supply a product to cure a disease or condition in an animal.

The requirement would provide that claims for alleviating, preventing or modifying the physiology of an animal may only be made when substantiated by robust scientific evidence. The Agvet Code currently provides for veterinary surgeons to have access to appropriate products (registered or not) to treat animals under their care, in accordance with the state and territory laws (e.g. single animals in food producing species).

### Manufacture and supply

The requirement for manufacture would recognise that a variety of approaches may ensure the quality of product manufactured, including:

APVMA licensing,

international feed manufacture standards

domestic industry codes of practice.

### Labelling

The requirement for labelling would detail information to be included with the product that would allow people who interact with the product (use, transport or storage) to make informed decisions about that product. For example information on the safe use of the product.

### Ingredients

The requirement for ingredients would ensure that the components of a product are sourced from lists of substances (international or domestic) considered appropriate for inclusion in animal feeds or human food. Where a quality standards (such as minimum purity) exist for a substance, those will be a requirement for that ingredient.

The timeframe for implementation is estimated as one to four months from date of decision, but not earlier than 1 January 2015.

## Option C – Legislative reform – registration as listed chemical product

This option would regulate nutritional/digestive stock food products as listed chemical products, a lower regulatory burden pathway than registration.

Listed chemical products must conform to a prescribed standard that defines an acceptable risk approach for a class of chemical products and prescribes risk a common risk mitigation strategy for

all the products in the class. However, unlike the self-determination approach (Option B), the APVMA would determine pre-market if a product is consistent with the standard. APVMA's evaluation would routinely require (based on existing experience for existing listed chemical products) information to establish consistency with the standard.

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. A standard could, but would not be obligated to, prescribe the criteria described for the self-determination reform described above[10].

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).

## Section 5: Impact analysis

Each option has been assessed against its ability to address the regulatory imbalance between industry and government effort and controlling risk for some stock food products. The imbalance arising from an ability to utilise a standard approach to risk mitigation rather than bespoke individual assessment.

The costs and impacts discussed here have been identified through consultation with:

users, manufactures and suppliers

veterinary health care professionals

government, including the APVMA and the Australian Bureau of Agricultural and Resource Economics and Sciences (ABARES).

For the purposes of analysis the status quo (Option A) has been taken as the baseline, rather than calculating the value of all options relative to no regulatory engagement.

### Option A – Status quo

The status quo does not address the issue of effort vs risk and would maintain the:

- detailed, specific bespoke pre-market assessment of products
- management of risks to human and animal health, environmental safety and Australia's trade reputation on an individual product basis
- costs for data generation, application fees, annual levies, registration renewal fees and manufacturing licence application and maintenance costs for industry
- the assessment and administrative costs, and revenues, for APVMA.

[10] For the purposes of analysis it has been assumed that no additional controls other than those outlined in self determination (Option B) would be proposed in the listed chemical product standard.

The status quo maintains any potential barriers (as identified by industry and the Productivity Commission) to the introduction of innovative products into Australia.

Anecdotal information[11] from the manufacturing and supplying industry indicates that while the costs of compliance are not outweighed by the potential enforcement penalties, this is not sufficient to seek registration of these products. Rather these products would never be introduced to the market as there is likely to be insufficient return on investment.

Under the status quo the participants in the NRS will continue to respond to non-compliance consistent with the risk approach of each responsible agency. Access to a wider range of response compliance tools for the APVMA (introduced in 1 July 2014 allowing other effective options than only prosecution or recall) will allow for proportional responses to manufacturer or supplier behaviour. Similar options exist to address users of products at the state and territory level.

It is expected that the current level of compliance engagement would continue across all participants of the NRS. As noted in section 2 the current enforcement practice has resulted few significant events and coupled with Australia's strong trading reputation for clean produce, indicates the effectiveness of risk mitigation of stock food products.

The status quo is also not responsive to stakeholder needs as outlined in section 3.

## Option B – Self-determination

The removal of pre-market regulatory engagement and the adoption of an industry self-determined model address the core problem of regulatory effort in comparison to risk. However this approach may appear to result in a regulatory environment with an increased risk of the product from that of the status quo. The design of the criteria for each aspect maintains the controls afforded by the APVMA assessment on a holistic individual basis, through a standard approach to the individual risks.

Animal safety and welfare is a key risk that may be impacted by the method used to introduce food for consumption by the animal. Some methods (such as intraruminal bolus or syringe or stomach tubing) require a degree of veterinary experience or animal husbandry that is not present within the wider community. Products using these methods of delivery would not form part of the reform.

The ingredient aspect draws upon the international approach to animal feeds. Lists of suitable ingredients, their purpose and quality, are routinely used by international manufacturers and suppliers. The lists are prepared by jurisdictions with a comparable approach to risk, and who have a strong presence in global trade of produce. This aligns Australia risk approach for ingredients with our international competitors.

Some ingredients, such as hormones, antibiotics (other than for feed preservative) and vertebrate animal material for consumption by ruminants would also not be permitted in these products. This would maximise the safety of the products and minimise risk to trade and anti-microbial resistance.

[11] Industry discussions with the department in development of reform option

Quality of ingredients, and the potential presence of impurities, is a source of risk for animal welfare, human health and Australia's international trade. A cascade of quality specifications, starting with the Australian standard (if one exists), to a standard by an Australian state or territory, ending with the most stringent listed standard for the ingredient. This provides that rather than the APVMA assessing the risks of the quality of an ingredient multiple times across a range of products, an acceptable quality is set for all ingredients of the product.

The use of professional judgement, in the form of a veterinary surgeon, or substantiation through robust scientific evidence provides controls on risks to animal welfare. The most extreme of claims, curing a condition, are restricted only to the professional judgement of the treating veterinary surgeon.

The majority of veterinary chemical products are currently required to be manufactured at licenced facilities, or at facilities that have been independently audited to comply with good manufacturing principles. The need for quality assurance in the products for animals reflects the potential for risk to both animal and human health. The manufacturing aspect recognises that quality assurance protocols are an integral part of mitigating risks of stock food. This requirement may be addressed through a number of approaches, including existing APVMA licencing system, animal feed manufacturing industry code of practice or other international animal feed quality standards.

The nature of aspects for claims, labelling, ingredients and quality of manufacture are already familiar concepts in the current regulatory system for stock food manufacturers and holders of product registration.

The option draws upon other existing regulatory regimes (consumer law and control of use) and safety systems (residue monitoring and quality control practices).

The benefits of this option include:

reduction in regulatory costs to industry of $7.8 million

aligning pre-market and ongoing regulatory burden, effort and cost to the risks of using the product, without compromising protection of human and animal and health, the environment and trade

alignment with international approaches for similar products, facilitating access of international products, including innovative products, into the Australian market

facilitating entry of new products, suppliers and manufacturers through reduction of regulatory burdens and costs

recognition of the market as an effective control of the product through good product stewardship within the industry (suppliers and manufacturers) and common and consumer law

removing duplication of controls between the Agvet Code and other regulatory regimes

reflect the practices of a normally efficient business

implementation in early 2015 is possible.

The majority of regulatory effort and burden associated with the stock foods consistent with the five criteria would be removed, instead providing a practical degree of self-regulation (i.e independent of APVMA pre-market assessment) for industry[12].

### Value

The Feed Ingredients and Additives Association of Australia (FIAAA) and the Pet Food Industry Association of Australia (PFIAA) have provided information that the average costs to bring innovative products to Australian market are:

$200 000 for stock foods

$350 000 for pet foods.

ABARES estimated that the costs for generic versions of innovative products are 5 per cent of the original cost. Costs being reduced are through the ability to rely on previously assessed information. A review of a random sample of currently registered products estimated that 55 per cent of registered stock food products (around 380 products) could be consistent with the self-determination criteria.

Utilising these parameters ABARES estimated the annual value of red tape reduction for this option to be $7.8 million. Additional savings of up to $800 000 is possible in APVMA fees and levies. Annex A details the ABARES calculations and key assumptions.

The reduced regulatory burden of removing the necessity for data generation to support registration or the need for manufacturing facilities to be licensed by the APVMA 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. During consultation information was provided by a state government that some farms supplement their income through the production of blocks and licks (declared not to be a VCP currently, and proposed to continue under self determination). Similar business across the range of nutritional/digestive products may develop with the reduction in cost burden.

A consequence of self-determination is that the responsibility for the product shifts from being shared by government (through the APVMA assessment) and industry to focus solely on the manufacturers and suppliers (industry). Consultation with manufacturers and suppliers of stock food products has confirmed recognition of the increased product stewardship expectations and willingness to operate in such an environment as they consider their internal product stewardship arrangements are more onerous than those imposed by regulation.

The market impact of 55 percent of currently registered products remaining in the market as self-determined and therefore unregistered products is negligible. The products would be present before and after any reform. It may be anticipated, but is not assured, that the costs of products to consumers will reduce. This will be aided by an increase opportunity for competition from equivalent

[12] A manufacturer or supplier may choose to avail themselves of the APVMA technical assessment process to aid them in the self-determination. While this would attract a fee, the choice to do so would rest solely with the manufacturer or supplier.

products that have not entered the market due to the regulatory burden. Consultation with industry has identified no concerns regarding adverse competition effects, beyond those reasonably expected in a competitive market.

Industry has estimated that the presence of innovative products in the stock food market has the potential to improve feed conversion, effectively reducing the feed input cost to users by up to $10/tonne of feed[13]; equating up to a $100 million benefit to the animal feed industry.

### Government costs

It is expected that the government costs of approximately $40 000 will be incurred for developing the necessary legislative changes for this option. APVMA will experience a reduction in revenue (from application fees, levies, annual renewal fees)[14]. This will in part be offset by the reduction in expenses in assessing applications and administrative effort of processes for affected products.

### Specific areas of potential impact

The impact of this option to individual users (primary producers or pet owners) varies with the nature of the product.

The risks to trade or biosecurity arising from contaminated or incorrectly self-determined products (for example containing an ingredient not acceptable for stock food products without pre-market assessment) has the potential to adversely impact stock food users. These risks are mitigated through inclusion of quality standards (Australian or international) and the exclusion of higher risk ingredients from self-determined products. The ingredient criterion limits the ingredients of a product to those detailed in lists of substances fit for human consumption or appropriate for incorporation into animal feed.

The risks posed by low quality ingredients exist within the current regulatory environment. While criminal offence provisions (and related civil penalty provisions) exist for the supply of chemical product that do not conform to a standard, for many of the 'active constituents' in nutritional/digestive products no applicable standard exists under the status quo. The ingredient criterion of self-determination provides a more definite reference, reflecting routine practice of competent manufacturers, than the status quo.

Pet owners, relatively inexperienced in feed products compared with livestock owners, may believe that protections against product inefficacy could be reduced through the self-determination approach. The pre-market assessment of the APVMA ensured that some claims for a product were substantiated before access to the market. Self-determination has a similar level of protection through restricting supply of products claiming to cure a specific animal disease or condition only to veterinary surgeons. Pet feed products with claims for 'curing' are currently supplied through

[13] FIAAA discussions with department

[14] This value, and the corresponding cost to industry, is not calculated as part of the regulatory cost savings but is included for completeness

veterinary surgeries so no additional impost will be experienced by the pet owners in accessing these products.

Efficacy claims such as addressing obesity or reducing anxiety are considered to be within an owners' capacity to determine without specific veterinary expertise. Where these products lack efficacy, remedies through consumer and common law (as is the case for other products) exist, providing a clearer pathway for remedy by a user than the existing system. Similar to efficacy claims with a lesser immediate adverse consequence (for example vitamin and mineral supplements), the opportunity for veterinary intervention exists to mitigate risk to animal welfare.

Restrictions on the claims able to be made, and a requirement to substantiate specific claims (for example by referring to established evidence from publications or sound scientific studies) provide protections to users. The information to be contained on the label is considered the minimum required for the supply of a consumer or industrial product with similar hazards. These controls ensure appropriate and safe use would mitigate the potential risks to workers handling a product.

### Non-compliance

Industry (manufacturers and suppliers) have redress for the non-compliance of competitors through a variety of pathways, including peak body engagement, court injunction or reporting to regulatory authorities. Users who encounter products not 'fit for purpose' may seek redress, as is currently the case, through fair trading or consumer law provisions.

The opportunity for industry to access 'self-help' tools (peak body engagement and injunctions) complements the self-determination approach.

The opportunities for, and response to, non-compliance are discussed in detail in Section 8. In brief there are four broad categories that may be considered for non-compliance.

Unintended – The suppliers of these products with claims consistent with a VCP but do not intend for their product to be a VCP, and nor does it act as one.

Uneducated - The suppliers of these products would willingly comply with requirements and intend for their product to be a VCP but are unaware of any obligation for registration or avenue for self-determination.

Well intentioned – The suppliers of these products have incorrectly self- determined that their product is consistent with the five aspects.

Wilful – Suppliers of these products are aware their product is a VCP, is not consistent with five aspects and continue supply of the product.

The impacts of the reform at implementation for the first two categories are considered to be beneficial. The wider scope of self-determination allows supply of products that otherwise meets the definition of a VCP without the need for formal pre-market assessment by the APVMA. For suppliers of products in the 'unintended' category, they may either amend their claims to more accurately reflect the product, or amend their processes to allow the self-determination model to apply. These amendments may only affect manufacturing or quality assurance practices.

In the ‘uneducated’ category, the self-determination criteria may apply without any action on the supplier or manufacturers part; as the supply of the product may already be consistent with self-determination and is lawful. In other instances, as for ‘unintended’, the option for product suppliers to amend their processes to meet self-determination criteria to apply is available. The costs of pre-market assessment and interruption in the supply of product (and ultimately business operations) that arise from waiting on the conclusion of APVMA processes is avoided. This allows businesses to respond more efficiently to its drivers, rather than the timeframes of the regulator.

At implementation those suppliers who fall within the ‘well intentioned’ category will, inadvertently, be supplying product unlawfully as it is consistent with a VCP yet not consistent with the self-determination criteria. Nor is it a registered chemical product. The consequences of this would include some level of intervention (non-government or government). These suppliers will benefit from seeking APVMA technical assistance in their self-determination decision to educate future self-determinations, and reduce the potential for future compliance action.

Those suppliers in the last category, ‘wilful’, should reasonably expect consequences of compliance action this may be through non-government (industry or user) intervention (injunctions) or the regulator (infringement notices, court action).

### Risk profile

As noted previously the protection of human, animal and environmental health and Australia’s international trade are the first priority of agvet chemical regulation. Each aspect is intended to address one or more of these risk factors and combined they operate to ensure the level protection is equivalent to that currently achieved for the affected products. It is important to note that the reform would not affect all stock food products (based on analysis approximately half of registered chemical products could be eligible). The reform aims to respond only to those stock food products where the risk aspects are well understood and can be effectively mitigated through a standardised approach.

It is the acceptable risk level of each aspect that combines to creating a risk box (see Figure 3) . All products within the box have a known and understood risk.  Products outside of the box (in any direction) have at least one area of risk that warrants assessment. By defining the sides of the box through the requirements of the aspects industry is able to effectively and efficiently self-determine the need for registration (and related regulatory burden). Through adopting a conservative approach in the requirements (e.g. use of international lists of animal feed ingredients) the potential for risks to human, animal, environmental or trade safety are expected to remain equivalent to Option A.

Non-compliance (either deliberate or inadvertent) with the exclusion will, in general,constitute a risk to safety. This risk exists to the same, if not greater extent, under the status quo. For example no specific requirement exists for conformance with ingredient quality (as stated at time of pre-market assessment) for non-active constituents.  To introduce a level of regulation that would reduce this risk to zero would have the practical effect of compromising the financial viability of many manufacturers, with a related impact on users through increased costs of production for those that remain. It is appropriate, noting the existing effectiveness of status quo to achieve risk control (evidenced through lack of significant incidents) to retain the same degree of control. This option

provides greater clarity for manufacturers and suppliers (e.g. ingredient quality) to aid them in minimising risk.

## Option C – Listed chemical product

The listed chemical product option sits between the status quo and the self-determination options with a reduction in burden while retaining APVMA pre-assessment. As shown in Figure 1, the degree of regulatory enagement for listed chemical product is less than of a registered chemical product. In developing the options for reform the department considered that Option B (self-determination of exclusion from regulatory process) likely represented the greatest reduction in regulatory costs. It followed that any other regulatory approach (such as listed chemical product) would have reductions in cost less than Option B but largely operate in a similar fashion.

This option provides for a 'positive' regulatory engagement and retains direct control of product access in the Australian market place. By requiring a pre-market assessment of the product by the APVMA, albeit reduced in comparison to the status quo, the controls of the Agvet Code that apply to registered products and standard would continue to apply. The primary responsibility for addressing non-compliance remains with the APVMA.

The measures to achieve protection of health and environment may mirror those of self-determination, assuming the standard adopted has similar terminology. The concerns of misapplying self-determination to a product are removed through the involvement of an independent authority, the APVMA. This involvement will come at the cost of delays in market access, where none exist in the self-determination model. Reduced, but not trivial, assessment will delay the timeframe to bring a product into market and this will be further impacted by an applicant's ability to submit quality applications or respond to identified issues in an application.

It is estimated that this option would represent 50–75[15] per cent of the savings to businesses from the self-determination option. However, these savings will be delayed until the required standards to implement the 'listing' are developed.

### Government costs

It is estimated that the government costs would exceed that of self-determination ($40 000) in the development of the listed standard and subsequent legislative implementation. The level to which the costs to government would exceed self-determination is dependent on the extent to which it differs from the aspects developed for self-determination.

The APVMA would experience a slight reduction in application costs but would retain the revenue from levies and annual renewals[16].

[15] More detailed costings will be included in the RIS prior to decision on the reforms.

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

### Industry impacts

The impacts to suppliers and manufacturers are similar to those for self-determination. The value of the impacts is expected to be proportional less, similar in scale to the reduction in benefits (50-75 per cent). Under this option a product would require listed registration prior to lawful supply. No supplier will be able continue lawful supply through meeting the standards inadvertently, assessment will be required.

The costs of ongoing registration of the product as a listed chemical product (application fees, renewal fees, 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 be incurred, as listed chemical products are exempt from that requirement. A standard may require quality assurance practices as per the manufacturing aspect however, having the same practical cost to businesses in addressing a normal business practice.

Specific segments of industry believed[17] there is great value in the continued involvement of government in the pre-market assessment of stock food products in achieving protections for users and acting as a market access barrier to other potential players. However, the consensus opinion was that 'listed chemical product' 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.

Suppliers and manufacturers[18] also stated that any degree of pre-market assessment would impose restrictions on chemical access not experienced for similar products in competitive markets internationally.

In considering this option the increased protections (or perceived protections) compared to self-determination, to the community and the benefit to business of government imprimatur was weighed against the costs of regulation. While the listed chemical product option does represent a significant improvement from the status quo in aligning regulatory effort with product risk, any increased protection above that of self-determination is not outweighed by the costs and delays. The cost of regulation for listed chemical products is greater than for self-determination while achieving an equivalent level of protection.

## Section 6: Consultation process

Any reform to the regulation of stock foods and pet foods as veterinary chemicals will have a direct impact on a variety of stakeholders; from manufacturers and suppliers of products, to users and pet owners and consumers of produce. 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.

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

[18] Industry discussions with department over development of options

## Previous consultation

Targeted consultation has been conducted in the development and refinement of options. Consideration of all options presented in this RIS occurred through the consultation ongoing from November 2013.

The participants in the consultation were provided with iterations of a potential reform, each being informed by the feedback received on the previous versions. Participants were also invited to attend a workshop in February 2014 hosted by the department to discuss the reform principles and approach. The department has also had detailed discussions with interested participants. The participants in the targeted consultation are detailed in Annex B.

Consultation established as consensus amongst manufacturers and suppliers that the status quo was undesirable and explored both Option B and C. The majority of stakeholders considered option B to represent the best outcome. Option C was explored with the minority and was discounted by stakeholders as delayed, complex and retaining costs relative to Option B.

Government stakeholders have expressed concern through consultation regarding the potential for poor quality product and to ensure that mechanisms to retain the current levels of control of risk are included. These views are reflected in the design of the aspects proposed for Option B and C.

The consultation refined both options to improve the delivery of policy goals. The stakeholder refinements are discussed below:

### Recognition of Australian (national and state) feed standards

Stakeholders raised concerns for the existing controls of quality of product and that this may appear to be reduced in the reform options proposed.

The options propose standards for stock food ingredients to minimise the risk of poor quality (or contaminated) products. Any Australian standard (national or state and territory) would be relevant. In the absence of a domestic standard, the most stringent international quality standard must be applied to that ingredient. Where Australian specific risks are identified (e.g. the potential for contaminated ingredients being incorporated into product) an Australian specific control can exist.

### Involvement of veterinary surgeons for specific use patterns and control of supply of product

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. An equivalent level of rigor for stock food products post reform with claims of serious consequence to animal welfare (i.e. curing a condition), the professional judgement of veterinary surgeons will be relied upon.

Early versions of the reform limited the extent of claims possible for products to be considered in the reform and by extension limited the products that would be affected by the reform. During consultation the potential to engage the professional judgement of treating veterinary surgeons was

recognised as a mechanism to expand the scope of the reform and retain objective consideration of a claim.

This control provides for a level of risk management that is appropriate and consistent existing veterinary prescribing rights[19].

In general claims for stock foods to cure a condition are restricted to the pet food sector. Nutritional or digestive approaches 'cure' long term health conditions, not a factor in most stock animal situations.

### Additional listings of appropriate ingredients

PFIAAA and FIAAA advocated for the inclusion of ingredients listed in the Official Publication of the Association of American Feed Control Officials as representing a government endorsed system of ingredients that are routinely utilised in animal feeds. After reviewing the processes for the publication it was established that it is is 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.

The need for a domestically maintained list, recognising that Australia may have needs in animal feeds that differ from those internationally, was key point raised by stakeholders during consultation on the options. The risks of ingredients means it is appropriate that government, through the expertise of the APVMA, be responsible for maintaining and controlling the list. The costs for assessment will be recovered from those who benefit from the inclusion of the ingredient in the list (in that a product is not a VCP and not therefore subject to annual fees or levies). Inclusion of an ingredient would not necessarily ensure exclusive use of that ingredient by the party who sought its inclusion.

### Recognition of relevant industry code of practice and international manufacturing accreditations

A primary industry driver for reform was the application of a manufacturing quality scheme designed for pharmaceutical products being applied to feed products. The stock food manufacturing industry, independent of this reform, had been developing codes of practice as an alternative for the existing arrangements. In any reform model that increases the responsibility of the supplier, through decreasing the active involvement of the government, it is appropriate to consider relevant industry code of practice. 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.

Allowing certain international manufacturing accreditations to be recognised also reduces any unnecessary duplication of effort for compliance with multiple and comparable standards.\

[19] Veterinary surgeons 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.

### Estimates of costs, benefits and unintended impact of reform

Information provided by the FIAAA, PFIAA and APVMA allowed quantification of the existing costs of regulation and the potential benefits that may be achieved through the reform. The reform reduces the regulatory costs of nutritional and digestive stock food products. The remaining costs that a manufacture incurs in addressing the four aspects of claims, labelling, ingredients and manufacture are considered to be those of a normal efficient business.

Consultation highlighted that certain blocks and licks are declared not to be VCP, and are excluded from the need for licensed manufacture. 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 would exclude these blocks and licks from the requirement for a recognised manufacturing quality system.

## Future consultation

Significant targeted consultation has occurred in the development of the reform from November 2013. A wider public consultation will be held with the release of the draft regulations and this RIS. The AGGR suggests a consultation period of 30 – 60 days for any RIS. Significant levels of consultation have been conducted to date, including on the specific options to be considered (and the preferred option). With this breadth of engagement on the reforms in this instance a consultation period of 14 days is considered appropriate.

The consultation will be announced, and documents released, through the departmental website and via direct email to identified interested stakeholders.

All reform options are open for comment. Specific questions of interest to the future development of this RIS are highlighted in section 1.

Submissions from stakeholders will inform the final decision on proceeding with the reform. It is expected that implementation would at the earliest be 1 January 2015.

Significant changes or redevelopment will, necessarily, delay implementation and may require further consultation. Significant opposition to the preferred option, or a desire to retain the status quo, will be considered in the decision to proceed.

# Section 7: Preferred option

In determining the preferred option the net benefit to industry, community and government of each option was considered.

The preferred option is for a legislative reform allowing self-determination by industry of certain stock foods and pet foods. 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 costs for industry (~ $7.5–10 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, or to Australian trade to status quo.

By removing the time and cost required for registration, it is anticipated that this proposed reform will better facilitate access to innovative stock foods that increases the productivity of Australian farmers and promote health of Australian animals. The FIAAA and PFIAA, which represent the stock food and pet food industries have estimated that the proposed reform would result in the release of a backlog of 120 (100 stockfeeds and 20 petfoods) products that are currently not viable to register.

The APVMA currently registers over 350 stock food products and it is estimated that approximately half would be subject to this reform[20].

As discussed in Section 5, the reform reduces red tape, with the market overall seeing a reduction in regulatory costs. The burden of ongoing monitoring and compliance of excluded products is a relevant consideration in all deregulatory measures. In considering the reform, the variety of existing monitoring and regulatory systems in addition to those of the NRS were relevant. The regulatory systems addressing food standards, consumer law, civil legal action, exporting requirements and importing controls in destination countries are considered adequate to provide the control over the life of these products in the absence of direct regulatory engagement under the Agvet Code.

# Section 8: Implementation and Review

## Implementation

The implementation of the preferred option, subject to the Minister for Agriculture's agreement pending final consultation as part of this RIS, will be in four key stages.

### Release of draft regulations for public consultation

The department expects to release the draft amendment regulations for public consultation in October 2014. The papers for consultation will be made available on the department's website and via direct email to all participants of the reform development process to date.

The specific date of release is dependent upon drafting resources of the Office of Parliamentary Counsel (OPC) and will be informed by the wider reform agenda of the Australian Government. This risk will be managed through submitting a drafting bid for resources to OPC seeking priority in the drafting process. The submission will clearly identify the benefits of the reform and consistency with the government's agenda to reduce red tape.

[20] Based on average for last 6 years and a sample review of product ingredients.

### Refinement and finalisation of draft regulations and supporting documents

After consideration of the submissions from consultation, final draft regulations are expected in October/November 2014. Ministerial decision of the reform will be sought in November 2014 and will include the final version of this RIS. The legislative package, pending ministerial approval, is expected to be submitted for consideration at an Executive Council meeting in December 2014.

The key risk at this stage is that feedback received during the public consultation shows a lack of broad support for the reform or that a specific previously unidentified risk exists that warrants redrafting of the reform. Continued dialogue through the consultation process is considered the most effective mitigation for this risk.

### Conformance with government requirements

Australian Government requirements for a best practice approach to the development and introduction of regulation ensure that decisions regarding the regulation are informed of the need and consequences of any change. The process also ensures sufficient time for consideration of each stage in the process.

The risk is that key individuals or entities in the process are unavailable for their role e.g. through competing demands in wider reform agenda. This risk is mitigated through continued dialogue with stakeholders to ensure knowledge of progress and management of expectations.

### Implementation of relevant transitional arrangements

The need for this stage is dependent on the time between registration of the regulations and their commencement (currently proposed as 1 January 2015). Where any significant period exists between these dates transitional arrangements to provide clarity for stakeholders are necessary. An option would be temporarily exempting specific stock food products (consistent with the aspects of the reform) from the operation of the criminal offences and related civil penalties for supplying an unregistered chemical product.

The key risk at this stage is access to sufficient resources to effectively implement a transitional arrangement. The example provided could operate through the APVMA providing temporary exemption for products when holders of product registration notify the APVMA.

This risk would be managed through minimising the period between the regulations registered and their commencement.

### Commencement of regulations on 1 January 2015

The commencement of the reform is intended, at earliest, for 1 January 2015. The final date will be communicated through public release on government websites.

The primary risk to this stage is a delay arising fromthe preceding stages delaying commencement. . Management of this risk is through the management strategies in previous sections.

## Review

The performance of the reform policy will be evaluated based on achievements in range of objectives:

### Reduction in regulatory burden and improved efficiency

This reform was initiated by the needs of users and 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. This feedback will be harvested through department's ongoing stakeholder engagement process for the wider reform process, and may include surveys or meetings.

The APVMA's overall efficiency in assessments of other VCP 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 will act as an objective measure of the reform.

### Improved innovation and competiveness in the market

The presence of innovative products, or an increased variety of current products, in the market place will act as a measure of the success of the reform. Either will reflect the improved ease of market access. A measure for this will be stakeholder feedback on whether a decrease in nutritional or digestive products available internationally but not domestically has occurred.

An absence of criticism about overseas products not available domestically (a primary basis for reform) would also indicate effective delivery of increased opportunity for innovation.

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[21].

### 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.

While self determination provides for suppliers and manufacturers to accept responsibility for decisions regarding the need for pre-market assessment or otherwise, routine misapplication of the aspects will compromise the wider reform. Avenues exist for suppliers and manufacturers to seek specific APVMA advice in relation to a product. The APVMA, for a fee, may provide technical assessments prior to an application being made. The future application (though it need never be made) would be for registration of the product. Such requests for assessment may be made under 8AS of the Code Regulations as an Item 25 application.

[21] 120 products registered since 2008.

After commencement of the proposed reform, the use of this assessment by APVMA to validate a self-determination about a specific product will act as a measure for the understanding of reform. It will also provide information on the extent of aspects where new ingredients, claims or manufacturing standards are considered (and ultimately determined as not consistent with the aspects and the product is thus a VCP). This information may inform further areas for reductions in red-tape.

### 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.

There are four broad categories (as described in section 5) that may be considered for non-compliance.

Unintended

Uneducated

Well intentioned

Wilful.

The responding entity to non-compliance in all instances is not limited to the APVMA. The self-determination model encourages, and is predicated on, greater involvement of industry in product stewardship and affording users a variety of response options.

Engagement by industry and peak bodies with non-compliant suppliers or manufacturers to provide education in the self-determination model and the NRS more broadly would likely suffice to address non-compliance in most instances. Through industry monitoring of the trends of its engagement the effective implementation of the self-determination model can be measured.

Where this approach to achieve resolution fails (such as 'wilful' non-compliance) avenues other than direct government involvement are available to affected parties. Seeking an injunction (available to any party) presents an opportunity to test in court the consistency of a product with the five aspects of self-determination. The number and outcome of such legal action can identify a need for targeted government intervention.

For users of products not considered 'fit for purpose' remedies exist through fair trading or consumer law. The number and outcome of such action identifies the need for government intervention or additional quality control criteria in the aspects. Failure of the reform would be indicated by repeated instances of products self-determined as not VCP and being not fit for purpose (either lacking efficacy or presenting opportunity for harm to animals).

Regulatory agencies (such as the APVMA or state and territory control of use bodies) may undertake monitoring activities, randomly or in response to specific reports of non-compliance. This could

include review of any self-determinations, part of which may require access to information that substantiates the claims of the product.

While APVMA has a responsibility to manage products declared not to be VCPs any such action would represent a cross subsidy from fee paying participants of the NRS. Any APVMA engagement, as for all other regulators, would be in accordance with the risks posed by the non-compliance.

Residues violations will also act as a measure of the success of the self-determination model in effectively mitigating the risks of use of stock food products. Significant violations of residue limits would indicate both a risk to human health and the need for additional quality control measures.

Numerous systems already operate to monitor residues, by both industry (retail networks) and government. Existing protocols to respond to residue violations are considered adequate without the need for specific additional monitoring measures.

# 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 calculated the change in regulatory burden for the preferred option, that is, the full exclusion of certain stock food products from regulation. Under this option, stock food products that meet four specified criteria are considered to be of well-defined risk and excluded from the following Australian Government requirements for control of supply:

Registration with the APVMA

Payment of annual fee

Payment of annual levy

Certification of manufacturing facility under the Good Manufacturing Practice (GMP) standards.

Following discussions with industry it is assumed for the purposes of calculation, that 100 per cent of manufacturers would choose to utilise a quality assurance system other certified under Good Manufacturing Practice by the APVMA.

The exclusion of this segment of the stock foods market from the supply regulation removes any regulatory burden on the businesses involved. To quantify this 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. Before outlining how each of these costs were calculated, a discussion is required on the assumptions involved in determining the number of products impacted.

## Number of products impacted

Only some products in the stock food market currently regulated as veterinary chemical products would be excluded from regulation. To determine the proportion of products excluded, a random sample of products (42 of 383) was obtained and their respective ingredient lists reviewed. Only the ingredient aspect was reviewed, as all other aspects (labelling, manufacture and claims) are effectively addressed through registration and the associated pre-market assessment.

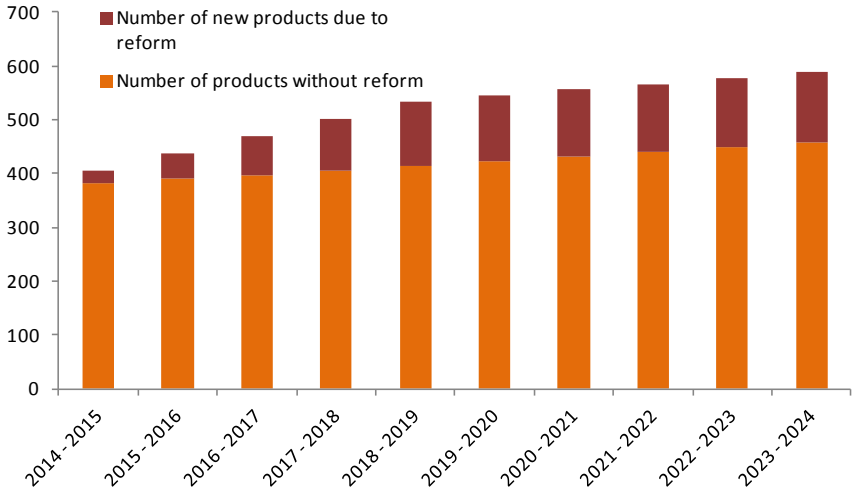
The department found 55 per cent of sampled products contained only ingredients present on one or more of the international lists of ingredients considered as appropriate for inclusion in stock foods. This proportion was used to calculate the number of products impacted by the reform.

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

The current regulations act as a barrier to entry for stockfood products. Discussions with the FIAAA and PFIAA indicate that the proposed reforms would result in the release of a backlog of 120 (100 stockfeeds 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 (Figure )
- This new market segment would grow at the same rate as the existing market once the backlog was released (Figure ).

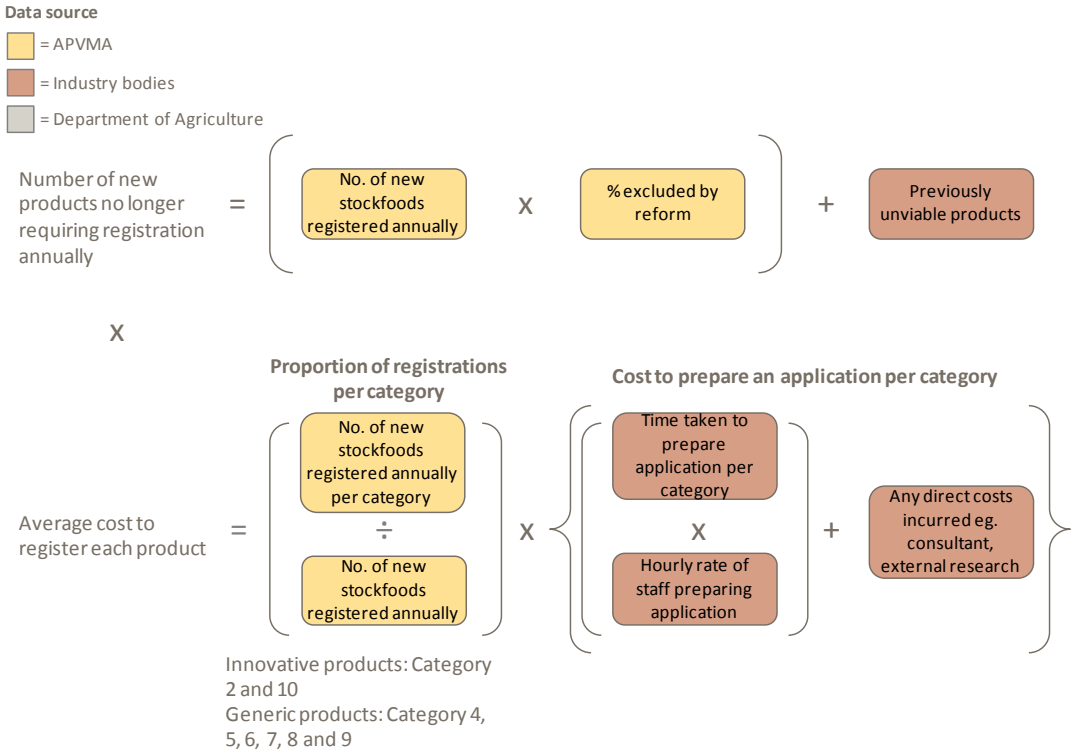
**Figure 3 Number of stock food products over the next 10 years**




## 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 ). Reference to category 9 is present for completeness of calculations, but no applications have been received by the APVMA across the sample window.

Figure 4 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 petfood 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 industry bodies surveyed their members to determine the average cost of preparing an application to register an innovative petfood and stockfeed. The estimates comprised registration preparation, consultant fees, research trials and dossiers to support applications. 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.

## Delay cost of registering new products

The methodology used to calculate the reduction in delay costs of registering new products is outlined in Figure 1. 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.

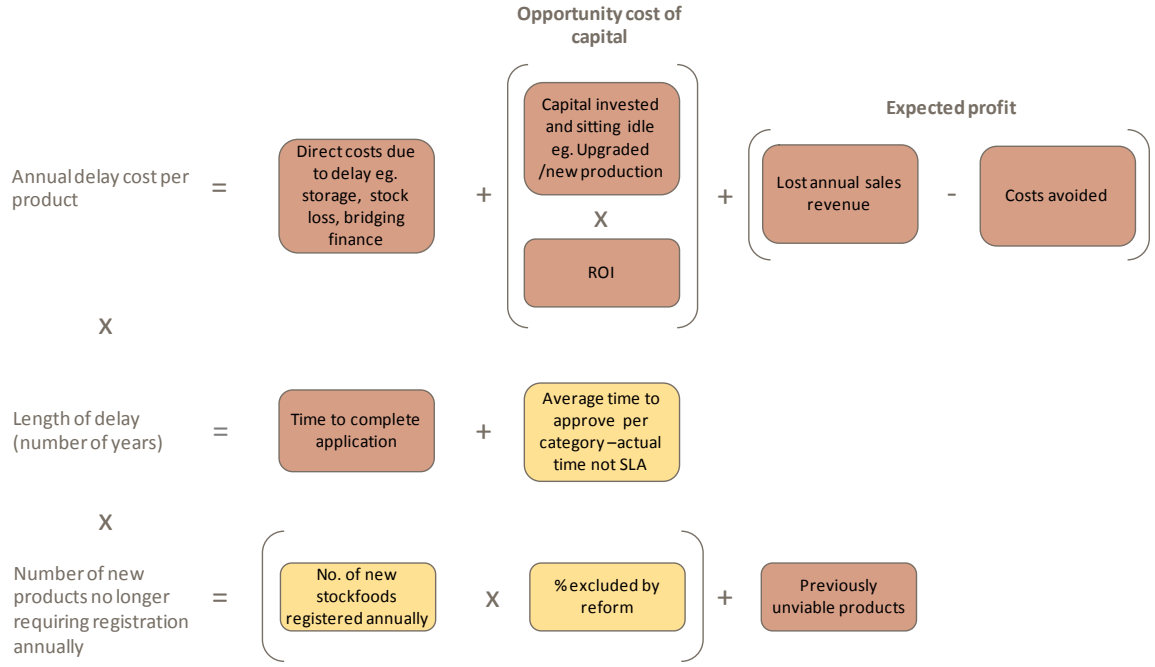
After speaking with businesses in the stock food industry, the calculation was significantly simplified due to the realities of the production methods used. For instance, it was determined that these businesses do not incur any costs or invest any capital before approval of the new product is granted 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 1 Methodology used to calculate the delay cost of registering new products

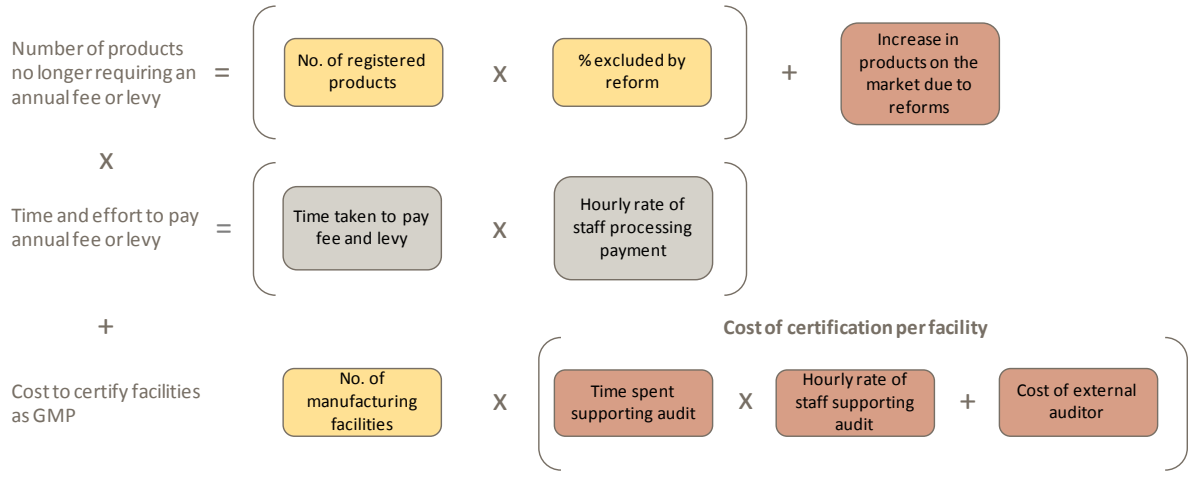



## Compliance cost of ongoing regulatory requirements

The reduction in compliance costs imposed by ongoing requirements (payment of annual fee and levy, and GMP certification) was a simple calculation (Figure 2). 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 2 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 |
|---|---|
| Animal Medicines Australia | Peak Body |
| Australian Lot Feeders Association | Peak Body |
| Australian Pork Limited* | User |
| Australian Veterinary Association | Peak Body |
| Feed Ingredients and Additives Association of Australia* | Peak Body |
| Inghams Enterprises Pty Limited* | User |
| Pet food Ingredients Association of Australia* | Peak Body |
| National Farmers Federation | Peak Body |
| Meat and Livestock Australia | Peak Body |
| Ridley Agriproducts | User |
| Rivalea* | User |
| Stock feed Manufacturers' Council of Australia | Peak Body |
| Australian Pesticides and Veterinary Medicines Authority* | Govt |
| Department of Agriculture * | Govt |
| State and Territory governments (VIC)* | Govt |
| State and Territory governments (QLD)* | Govt |
| State and Territory governments (WA)* | Govt |
| Chief Veterinary Officer - Australia | Govt |
| ACCORD | Peak Body |
| Animal Health Australia | Peak Body |
| Australian Companion Animal Council | Peak Body |
| Australian Egg Corporation Limited | Peak Body |
| Cattle Council of Australia | Peak Body |
| Dairy Australia | Peak Body |
| Pet Industry Association of Australia | Peak Body |

| Stakeholder/ Entity | Role |
|---|---|
| Sheep Meat Council | Peak Body |
| Veterinary Manufacturers and Distributors Association | Peak Body |
| State and Territory governments (SA)* | Govt |
| State and Territory governments (NSW)* | Govt |
| State and Territory governments (NT)* | Govt |
| State and Territory governments (ACT)* | Govt |