Implications of 'duty of care' for the development of new pasture species

Clinton Revell[1, 3] and Dean Revell[2,4]

[1] Department of Agriculture and Food Western Australia, 3 Baron-Hay Court, South Perth WA 6151 Email crevell@agric.wa.gov.au
[2] CSIRO Livestock Industries, Private Bag 5, Wembley WA 6913 Email Dean.Revell@csiro.au
[3] Centre for Legumes in Mediterranean Agriculture, University of Western Australia, Crawley WA 6009.
[4] CRC for Plant-Based Management of Dryland Salinity, University of Western Australia, Crawley WA 6009

Abstract
Pasture scientists in Australia have a successful history of pasture plant improvement that continues to this day. There are a large number of pasture varieties currently being evaluated for potential commercial release, and many of these are from species that have not previously been used in agriculture. The drivers of cultivar development include changing farm practice, new farming systems and the increasing need to manage environmental threats. These changes have coincided with an increase in risk aversion of agencies involved in plant improvement programs, which is perhaps motivated by acknowledging the general trend in society to use litigation as a means to resolve problems. It is therefore incumbent on pasture scientists, funders and administrators to take into account a reasonable level of 'duty of care' to avoid damage, injury or economic loss to end users or the environment. In this paper we summarise what is meant by the term 'duty of care' and in particular discuss how it relates to the development of new pasture cultivars, with a particular focus on southern Australia. We put forward a minimum set of measurements that should be undertaken, and discuss the circumstances under which additional investigations are warranted. The suggested approach aims to achieve a balance between meeting legal and social obligations without unduly jeopardising the timely release of new, improved pasture cultivars.

Keywords
Risk management, animal health, legumes, variety evaluation

Introduction
Improved or sown pastures and forage crops are used in both tropical (mostly subtropical) and temperate environments in Australia (Carpenter 1981). In southern Australia, breeding and selection has historically focussed on a narrow range of well established species such as subterranean clover (*Trifolium subterraneum* L.) and annual species of *Medicago* (medics) because of established research infrastructure and capacity for incremental cultivar improvement (e.g. early flowering, pest and disease tolerance). A wide ranging analysis of future pasture needs conducted within a farming systems framework has lead to resource reallocations and set up the opportunity for new species to be considered (Ewing 1999), many of which are yet to be domesticated.

Developing a broader range of pasture species for commercial release has coincided with other 'external' changes. These include a review of the permitted seeds list by Biosecurity Australia (Roberts 2006); greater awareness and concern over weed risk; an increase in risk aversion of administrators and funding agencies; and a more litigious society in general where real or perceived faults are more likely to be settled in court than in the past.

We are thus faced with a paradox: we are looking for pasture species new to commercial agriculture to satisfy specific, niche roles in agricultural systems, but at the same time society, or at least administrators, have tended to become more risk averse. Developing new species for new systems will inherently carry new risks, and these risks may be less defined at the start of the selection and breeding program than with 'conventional' species. So how can we find a balance between the timely delivery of new cultivars to industry and risk management? We have to ensure that addressing one set of problems does not introduce another, often equally significant, set of problems.

In this paper we argue that there is an obligation to follow a minimum set of tests to adequately show appropriate duty of care. This will reduce risk based on prior knowledge and provide an opportunity to detect other problems that might occur but were not anticipated. However, we cannot expect that such an approach will avoid problems from ever arising because, for example, the concentration of a particular secondary plant compound may vary and only lead to animal health concerns under somewhat

unpredictable environmental conditions. In setting guidelines, we must achieve a balance between risk management (i.e. duty of care) and the value and impact of new species and cultivar releases to industry.

The increase of 'alternative' plant species undergoing selection and breeding
The recent increase in the diversity of species under development should not be surprising. Francis (1992) reasoned that the reservoir of forage plant genetic resources must be widened in order to deal with new opportunities in agriculture, changing patterns of land use and emerging environmental threats. Despite the unequivocal success of ley-farming systems based on subterranean clover and annual medics, several contemporary factors have challenged their sustainability (Loi *et al.* 2005a). These include excessive dependence on herbicides, incomplete use of water and nutrients, pest and diseases and the high cost of seed production. A second generation of new annual legume species is being developed with a suite of 13 desirable characteristics (Loi *et al.* 2005a). Five new species are now successfully in commerce over 1.5 million ha in Western Australia (*Ornithopus compressus* L., *O. sativus* Brot., *T. glanduliferum* Boiss., *T. michelianum* Savi and *Biserrula pelecinus* L.) and two further species are under development (*T. spumosum* L. and *Trigonella balansae* Boiss.).

Current plant improvement programs are addressing (i) ease of seed harvest, deep root systems, hard and soft-seededness and grazing tolerance in annual legumes (Loi *et al*. 2005a), (ii) waterlogging and salt tolerance (Rogers *et al.* 2005), (iii) greater tolerance of soil acidity (Francis 1992, Loi *et al.* 2005a), and (iv) increased water use to reduce ground water recharge (Cocks 2001). Some of the genera highlighted by Cocks (2001) and under evaluation by the CRC for Plant Based Management of Dryland Salinity (CRC PBMDS) include *Lotus*, *Trifolium* (spp. *burchellianum* Ser., *hybridum* L., *ochroleucum* Huds., *physodes* Stev.), *Psoralea*, *Dorycnium*, *Swainsona* and *Cullen*. These lists are extensive since there is limited knowledge about the likely success of any particular species and there is a wide range of target niches.

In a review of the fodder options for salt-affected areas of southern and eastern Australia, Rogers *et al.* (2005) indicate that the historical management of waterlogged and saline lands has been based on two grass species (*Puccinellia ciliata* Bor (1) and *Thinopyrum ponticum* Popd.) and four legume species (*T. fragiferum* L., *T. michelianum*, *T. resupinatum* L. and *M. polymorpha* L.). Apart from puccinellia they are all relatively salt sensitive. They indicate over 100 other grass, legume, herb and shrub species (collectively) as high priority research targets, most of which are yet to be domesticated.

What is meant by 'duty of care'?
Duty of care is a concept that developed as part of the common law of the United Kingdom (Bates 2001). It became part of the common law of Australia early in the nineteenth century and the concept has continued to evolve in the Australian courts. The concept has been translated into legislation principally to clarify the law regarding liability for personal injuries, most notably in the area of occupational health and safety.

The common law duty of care requires that individuals take all reasonable and practical steps not to injure the person or property of another. The common law actions in trespass, nuisance and negligence are founded on such a duty. Action in negligence has defined and continually redefined the meaning and legal limits of the duty of care (Bates 2001).

The most likely civil cause of action against an organisation will be an action alleging negligence. Under the common law of negligence, three questions are invariably asked;
a) Was it foreseeable that the action of a particular person or organisation would expose another party to harm or damage?
b) Is there a relationship of 'proximity' between the two parties?
c) Is the action or inaction of one party the cause of the other party's damage or loss?

The standard of care expected is that which is reasonable in the circumstances (Bates 2001). This means that the more hazardous an undertaking, the higher the standard of care that may be required. In the case of a new pasture species we expect that the 'standard of care' is based on predictable hazards given current knowledge at the time, rather than a retrospective assessment if a problem occurs sometime after commercialisation. However, thorough consideration of potential hazards will still need to be

demonstrated and documented to avoid later accusation that a particular hazard should have been predictable prior to commercialisation.

In assessing whether the requisite standard of care has been met, evidence of industry practice will be relevant but not conclusive (Bates 2001). For example, general practice can be shown to be negligent, where industry practice does not keep abreast of increased awareness of dangers and the introduction of new technology that might lessen the risks. To show that duty of care has been met, an individual or organisation must be able to show 'due diligence' that they have assessed potential risks from their activities and then taken reasonable and practical measures to avoid, or at least minimise, those risks.

Application of the concept of duty of care to the environment is not well established. Common law does not recognise, and never has recognised, that a duty of care may be owed to the environment *per se* (Bates 2001). Impacts that arise out of conduct that adversely affect the environment are actionable through the harm to personal interests, not the harm to the environment *per se*. However, some state legislation (eg Environmental Protection Acts) extends the common law responsibility into a regulatory requirement requiring everyone to exercise a general duty of care to prevent harm to the environment.

What are the key areas for which 'duty of care' might apply to pastures?
We define four main categories for which duty of care associated with commercialising new pasture cultivars should be assessed. These are: (1) consequences for animal productivity or health; (2) potential to become an environmental weed or an unmanageable crop weed; (3) potential for problems in managing the agronomic performance or health of the plant and; (4) the capacity to maintain the 'integrity' of the cultivar.

Consequences for animal production and health
New pasture cultivars are often developed to improve animal productivity, but assessments are typically made by measuring biomass production of the cultivar under a range of environmental conditions, and quantifying nutritive value traits such as digestibility of dry matter and crude protein content. In some cases, palatability is assessed, but this is usually based on subjective or anecdotal information. Pasture species may affect livestock in a range of ways, including feed intake, liveweight change, wool growth and quality, meat and milk tainting, reproductive performance or organ damage. Such effects may be due to nutrient balance, plant toxins, or 'secondary' toxins associated with fungal or nematode infections.

Lengthy grazing studies prior to commercial release of cultivars are not routinely undertaken, largely because of the cost of doing so. However, we contend that an acceptable level of duty of care should involve grazing with the target animal species (e.g. sheep if the pasture is targeting the sheep-wheat farming system or cattle if it is targeting the dairy industry). The scale and measurements undertaken in such grazing studies should depend on the pasture species being investigated, an issue we address later in this paper.

Potential to become an environmental or crop weed
The potential for exotic plant introductions to become environmental weeds has a very public profile, aided in recent times by the CRC for Australian Weed Management. Over 28,000 plant species have been introduced into Australia, nearly 10% of these have become naturalised and over 300 have been declared 'noxious weeds' (Martin 2003). While most of these have been introduced either accidentally or for ornamental or horticultural reasons, the importation of pasture species has not been without fault. Minimising the risk of pasture species becoming environmental weeds is essential and a balanced weed risk assessment is desirable. The importation of exotic plants into Australia is regulated by the Australian Quarantine and Inspection Service (AQIS). A weed risk assessment protocol is central to this process and the tightening of regulations from the Prohibited List system to the Permitted List system in 1998 and now the reassessment of individual species in Permitted genera (Roberts 2006) will be the first filter for pasture scientists. Regulations at a State level may become a second filter. The CRC PBMDS is developing an internal weed risk assessment process for permitted species (Lynley Stone *pers. comm.*) and such an approach could be embraced by other agencies.

At the farm level, the potential of the pasture species to become a crop weed needs to be understood. Indeed recent economic research undertaken by the CRC for Australian Weed Management has

established that weeds cost Australia $3.9 billion per year in lower farm incomes and higher food costs (Sinden *et al.* 2004).
In this regard the herbicide tolerance of new species and the capacity for pastures used in cropping systems to be controlled by conventional in-crop herbicides needs to be defined. Knowledge about seed bank persistence is also important. Another crop-weed issue is the potential for pasture species to cause taint of crops through contamination. Where this is possible, there is a need to define the causal compound(s) and understand the factors that influence the expression of these compounds (e.g. genotype and environment).

Pasture agronomy and plant health
Pasture agronomy and plant health lie at the core of productive pasture systems. Species or variety evaluation is usually undertaken with agreed protocols for measuring herbage production, seed production and persistence. Pasture legumes require the provision of an effective strain of rhizobium, preferably with documented performance when associated with naturalised soil rhizobia. An important element is the screening for susceptibility to known pathogens such as red-legged earth mite (*Halotydeus destructor* Tucker), lucerne flea (*Sminthurus viridus* L.), aphids (e.g. *Acyrthosiphon kondoi* Shinji), nematodes, clover scorch (*Kabatiella caulivora* Kirchner) and common root diseases (e.g. *Phytophthora clandestina* Taylor). For species new to agriculture, a literature search for potential plant pathogens at a genus level will be an additional requirement with subsequent plant testing. Other desirable information will include aspects of plant nutrition and fertiliser response, herbicide tolerance, response to grazing and the provision of guidelines to industry for the efficient production of seed.

Cultivar integrity
Cultivar integrity relates to the ongoing role of the cultivar in meeting industry expectations and the need to maintain the genetic purity of the cultivar over time. This includes the maintenance of germplasm or breeders seed in Genetic Resource Centres and the provision of an ongoing supply of pre-basic or basic seed meeting the minimum standards for purity and germination.

Where to now: solutions must be acceptable and realistic
Duty of care with the commercial release of pasture cultivar must meet a ‘standard of care which is reasonable in the circumstances’ (Bates 2001). Despite differing perceptions and expectations, it is important that all potential problems *identified from prior knowledge and data* be investigated thoroughly by those developing the cultivar. This information and the responses of the development team (e.g. plant selection protocols) must be declared so that end users of the product are not subjected to unexpected harm, damage or economic loss. Problems with a new cultivar that are not able to be predicted from prior knowledge may still arise, but we contend that such situations are outside of what could be considered ‘reasonable’.

A central issue, we believe, in addressing the issues of duty of care in the commercial release of pasture cultivars is to accept the legal obligations whilst maintaining a practical and realistic approach. This is challenging and may lead one to think that the only solution is for all cultivar releases to be preceded by comprehensive, time consuming and costly analyses to minimise risk. We argue that such an approach is unrealistic given the constraints of resource availability: financial, time and personnel. Furthermore, taking such an extreme approach will carry significant tradeoffs, particularly in relation to the number of pasture products released (with limited funds used for fewer, more expensive studies) and the timeliness of releases (longer ‘lag’ time between identification of a problem and a commercially available solution).

We suggest a minimum data set should be collected as part of all variety evaluations. The need for additional data sets, though, depends on the particular circumstances of each case. If a new variety is from a species already in commerce, for which there is a knowledge base and experience, and for which there are no known problems, then only the minimum set of measurements should be undertaken (these are discussed below). If the knowledge base suggests that certain problems with that species have occurred in the past (e.g., oestrogenic plant compounds), then the variety should undergo appropriate screening (*Additional data, situation 1*). Grazing trials should only proceed if the variety is considered safe based on published data and documented experiences. If the variety is developed from a species that has not been used extensively in agriculture, then greater caution is required and a more structured and defensible approach is required (*Additional data, situation 2*).

Recommended 'minimum set' of measurements

(i) Herbage production / maturity (at least 3 data sets – sites x years)
(ii) Nutritive value of edible plant material (*in vitro* digestibility of organic matter and crude protein)
(iii) Seed production (at least 3 data sets – sites x years)
(iv) Regeneration/seed bank longevity/hardseededness (at least 2 years data)
(v) Flower / burr / pod characteristics
(vi) Herbicide tolerance
(vii) Rhizobial compatibility
(viii) Susceptibility to known pathogens (leaf and root diseases - fungal and viral, insect pests – red-legged earth mite, lucerne flea, aphids, nematodes)

As an example of the type of additional data that should be collected, we focus on duty of care as it relates to animal production and health. Other 'additional data sets' will be required for other issues, such as weed risk or potential to taint crops.

Additional data set; situation 1. Variety evaluation from species already in commercialisation but where previous animal health issues have arisen (e.g. fertility problems with phyto-oestrogens)
The eight series of measurements outlined in the minium data set should be undertaken and, in addition, plant selection and/or breeding should include an analysis of known (species-specific) anti-nutritional factors (ANF) such as phyto-oestrogens. In these situations, we would also recommend at least one grazing trial prior to commercial release, especially if the synthesis of a plant compound of interest may be inducible under 'typical' field conditions but may not have been detected at concentrations to cause concern under controlled glasshouse or plot trials.

Additional data set; situation 2. Additional data sets to support variety evaluation from species not yet commercialised
Requirements in addition to those described above will need to be determined on a case-by-case basis according to the extent of information published in the literature. Where there is little information for guidance, the additional set should include:

1. Published (or verified unpublished) data from plant analysis for the most widespread anti-nutritional factors and plant compounds causing animal health problems (phyto-oestrogens, coumarin, hypericin, condensed tannins). Single point analysis is acceptable if the samples were taken at a time when concentrations were expected to be highest, but measurements should still span at least three combinations of years and sites. If factors affecting the variation in concentration are not known, then more frequent time-course measures should be undertaken to span plant phenology, season and site.
2. A grazing study over green and dry feed periods comparing new species with an appropriate standard.
   - Measurement of liveweight change, wool growth and vegetable fault
   - Plant sampling for *in vitro* digestibility of dry matter or organic matter, crude protein, acid and neutral detergent fibre, and nitrates at key vegetative stages of plant growth and after senescence.
   - Blood sampling for liver function, trace elements, urea, creatine kinase
   - Meat taste testing according to industry standards
   - Retain a bank of pasture and blood samples for a minimum of three years

If the species has either a known history of plant compounds causing animal health problems, detected concentrations of the ANF(s) are above minimum standards, or there are unidentified compounds apparent, the grazing work should be conducted over two years. When appropriate (i.e., if the compounds can affect reproductive performance), a reproductive study may be justified. Grazing should be conducted under environmental conditions that are most likely to lead to high concentrations of the ANF(s). Additional studies will need to quantify the variation in the ANF(s) associated with environmental conditions (e.g., plant spoilage if the ANF requires fungal spoilage), season and/or plant phenology. It would be desirable to conduct controlled pen studies where the dietary concentration of the plant chemical can be manipulated and related to specific animal responses.

The method of pasture sampling should ensure that the ANF(s) under investigation is not chemically altered by the sampling procedures. Unless there is clear evidence to the contrary (based on prior experience), pasture samples should be placed on ice (or refrigerated) at the point of sampling and frozen

as soon as possible, or if possible, frozen at the point of sampling. Frozen plant material should then be freeze-dried until the effects of heating (and general handling) on the compound(s) can be quantified.

Cultivar owners would be expected to collate and archive all information associated with Duty of Care in a central location for a period of at least 10 years. This will be important in the event of problems emerging some time after commercialisation. The protocols described above should reduce, but not completely remove the risk of potential negative effects on animal health or performance. An alternative approach is to develop management strategies that producers can adopt should a problem arise or, preferably, a strategy to prevent the problem from occurring. It will be important for breeders to consider possible management strategies when risks in particular products are identified. Gland clover (*T. glanduliferum*) cv. Prima is a case in point where growers are encouraged not to conserve legume dominant stands for fodder (Nutt and Loi 2002) since it contains coumarin (albeit at very low concentrations).

'Road testing' the recommended protocol

To determine if the suggested approach would be effective, it is informative to consider four case studies of development in annual pasture legumes. The first (subterranean clover – *T. subterraneum*) is historical, the second (biserrula – *B. pelecinus*) is an example of a recent release that has experienced some occasional problems with animal health. The third (gland clover – *T. glanduliferum*) is a recent release that did involve a duty of care component. The fourth (bladder clover – *T. spumosum*) is an example of a current species being considered for commercialisation.

Subterranean clover

Pastures dominated by subterranean clover cultivars with a high content of phyto-oestrogenic compounds can be associated with grossly impaired reproduction in grazing sheep – infertility, dystocia and perinatal lamb losses (Reid 1981). The problem emerged in the 1960s and 70s following the release of cultivars such as Dinninup, Dwalganup, Yarloop and Geraldton, which lifted pasture productivity but contained high concentrations of the isoflavones genistein, formononetin and biochanin A. If the protocol proposed above had been followed it would not have avoided the problem because it was an unknown at the time (only the minimum data set would have been identified as being required). However, since that time the problem has been widely researched and knowledge of the causal link has informed subsequent cultivar development. All new legume species and cultivars are now (or should be) routinely screened for the presence of isoflavones, and only those with low concentrations proceed to commercialisation ('Additional data; situation 1').

Biserrula

Biserrula was developed in Western Australia during the 1990s and at the time had no history of agricultural use any where in the world. It is very productive and has a range of desirable features including high seed production, adaptation to a broad range of soil types, a deep root system and grazing tolerance (Loi *et al.* 2005a). Extensive agronomic studies were undertaken and biserrula pasture was grazed but we are not aware of any formal grazing experiments being undertaken. Several years after commercialisation of the first cultivar Casbah in 1997, a small but growing number of cases of photosensitisation have been recorded in ewes and lambs grazing biserrula dominant pastures in spring (Loi *et al.* 2005b). Could this problem have been predicted? If our protocol had been followed ('Additional data; situation 2') a formal grazing experiment may have highlighted this particular animal health issue, but there would have been no guarantee because the occurrence of the problem is sporadic and the plant chemicals in biserrula that predispose animals to photosensitisation are not yet known. Without this prior knowledge, the hazard was not predictable and even now it is not straight forward to establish an experimental model to elucidate the underlying mechanisms. It is, however, incumbent on researchers (and research funders) to establish the causal link between biserrula and photosensitisation in order to inform the selection of new biserrula cultivars and/or develop appropriate management strategies.

Gland clover

Gland clover is another recent species first developed for agricultural purposes in Australia. Its most outstanding feature is its resistance to red-legged earth mites, thought to be related to coumarin compounds in the plant (Wang *et al.* 1999). Given the state of knowledge about the impact of coumarins on feed intake, tainting of produce and the toxic effects of conversion to dicoumarol, extensive testing

was conducted to establish that concentrations in the plant were low and unaffected by spoilage (Nutt and Loi 2002). A detailed grazing study (in line with our suggested protocol for 'Additional data; situation 2') was also conducted to compare the animal production (liveweight gain and wool growth) and meat quality of sheep grazing gland clover with a similar group of sheep grazing subterranean clover (Masters *et al*. 2006). This experiment found no negative impact of gland clover on animal production or meat quality and to date, we are not aware of any negative experiences that have been recorded in commercial practice. This is the desired outcome.

Bladder clover
Bladder clover is a new species to agriculture at an advanced stage of development in the National Annual Pasture Legume Improvement Program. Agronomic and standard screening evaluation has been conducted to establish its merits in terms of productivity and persistence. This species, as for gland clover, falls within the guidelines of 'Additional data; situation 2', although with an additional variation. Bladder clover is from a genus with known animal health issues and has been tested for phyto-oestrogens (as described for subterranean clover). While the concentrations of phyto-oestrogens appear low, the presence of other secondary compounds became apparent in the isoflavone analysis. These needed to be investigated to inform the type of grazing study required to demonstrate a sufficient standard of care. The secondary compounds appear to be coumarin derivatives (S. Wang pers. comm.) and the minimum grazing study will shortly proceed with the additional measurements of meat quality and animal health indicators (including blood chemistry).

Implications of using our recommended protocol

Issues for funders
It will be necessary to recognise that 'duty of care' activities are part of doing business. They cannot be considered as a discretionary element of a research program or an 'optional extra'. Duty of care activities will generally be resource intensive because they will often involve livestock experimentation, and so there will be additional costs that need to be recognised and budgeted.

There may be circumstances where investigations of a variety will lead to its rejection from the commercialisation pipeline. It is therefore unsound to base funding of the duty of care activities on post-commercialisation cost recovery (such as royalties) because this would place pressure to proceed with commercialisation irrespective of the investigative outcome. A better strategy is to allocate additional funds to cover the necessary duty of care activities during the course of the selection and breeding program, recognise this extra contribution through an increase in equity share amongst partners, and where appropriate reinvest this income into pasture improvement programs.

An additional reason for duty of care work to be specifically designed into evaluation protocols is to avoid unnecessary delays in cultivar release; i.e. duty of care assessments should coincide or precede final stage field evaluations and the seed increase phase of cultivar development. This does not mean duty of care work should necessarily commence at the early stages of plant selection, because it may prove to be unnecessary if a new species or line is not developed for other reasons. But as soon as a line shows promise based on other measures, such as agronomic performance, then a complete duty of care program should be developed.

Issues for research
Duty of care will commonly involve the input of specialists in skills, for example, plant chemistry and plant pathology, that have been downgraded over the past decade or so following funding cuts. We believe there is a strong case for developing a coordinated team of specialists that can provide expert inputs into duty of care issues because all duty of care activities will have a common core of concerns even though the detailed protocols will differ between varieties. We argue that it will be more efficient to maintain core capabilities that can feed into a range of breeding programs across the nation than having to establish (or re-establish) the expertise for each case or breeding program. We consider that a national 'team' that spans research institutions and technical expertise to avoid conflicts of interest or 'patch protection' would be very valuable, and indeed scientific rigour will be critical to ensure the validity of conclusions.

Issues for administrators
Agencies involved in the commercial release of pasture cultivars will need to be cognisant of the fact that, even with the adoption of agreed protocols in duty of care, there remains a risk of problems emerging after commercialisation. In extreme cases, this may involve litigation. The cost of responding to emerging problems needs to be considered and management plans developed.

Issues for producers/industry
As for administrators, producers will need to recognise that there remains a risk, albeit reduced if new protocols are adopted, of problems emerging after commercialisation. Further minimisation of risk, however, will involve a considerable trade off between the detail of information accompanying a new cultivar and the rapid availability of new cultivars.

Conclusions
Pasture scientists and research providers have an obligation to ensure that an appropriate standard of care is demonstrated at the time of commercialisation of new species and cultivars to minimise the risk of harm, damage or economic loss for farmers, community and the environment. We have suggested a framework validated with field experience within which to work. The set of minimum measurements supplemented with additional animal health studies where necessary aims to achieve a balance between meeting legal and social obligations without unduly jeopardising the timely release of new, improved pasture cultivars. We cannot guarantee that this approach will prevent all problems with new cultivars occurring but such a level of testing should ensure a sufficient standard of care at the time of commercialisation.

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