GLOBAL HARMONISATION IN THE FIELD OF INVASIVE SPECIES MANAGEMENT PRODUCT DEVELOPMENT

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Abstract: Problems associated with managing vertebrate invasive species, defined as any exotic or native species that has spread beyond its natural range, are remarkably common around the world. Although the species may differ, the niches they fill and the damage they generally cause is often consistent. As such, a possibility exists for greater collaboration and harmonisation in developing new tools to manage the impacts of invasive species. Moreover, the considerable expense of developing new products, the often onerous registration process, and the lack of return on investment leading to market failure has meant that progress within the field of invasive animal management product development can sometimes be stifled. This paper details a potential way forward using specific examples of ways the Invasive Animals Cooperative Research Centre (IACRC), Pestat P/L, and other IACRC commercial partners aim to provide overseas organisations with humane non-lethal and lethal wildlife management tools. Conversely, we detail overseas-developed products currently being tested in Australia, and a proposal to keep abreast of new developments in other countries to ensure invasive species management within Australasia remains of the highest level. This can only be achieved through truly collaborative research and the global harmonisation of registration packages, so product development costs can be minimised and the necessary scales of production can be attained.

Key Words: collaboration, harmonisation, Invasive Animals CRC, invasive species, pesticides, product development, registration.

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INTRODUCTION

The World Conservation Union (IUCN) defines invasive species as *organisms (usually transported by humans) which successfully establish themselves in, and then overcome, otherwise intact, pre-existing native ecosystems* (www.issg.org). This paper, however, takes a broader definition, and one that is consistent with that of the Australasian Invasive Animals Cooperative Research Centre (IACRC). In the context of the IACRC, "invasives" refers to terrestrial and freshwater vertebrates, including overabundant native species. While not always transported by humans (although many have been accidentally or deliberately introduced to areas beyond their natural range), overabundant native species have generally become such through a direct result of habitat changes that positively influence that species' ability to survive and reproduce. The IACRC aims to counteract the impact of invasive animals through the development and application of new technologies and by integrating approaches across agencies and jurisdictions (Saunders et al. In Press).

Currently, Australia is host to 56 invasive vertebrate animal species. Most agricultural sectors suffer significant economic losses through factors such as predation of livestock, crop damage, and competition for feed by invasive species. Furthermore, in the last two centuries, 27 indigenous mammal species have become extinct in Australia, accounting for over half the mammalian extinctions in the world over that time period. The invasive red fox (*Vuples vulpes*), feral cat (*Felis catus*) and European rabbit (*Oryctolagus cuniculus*) are three species that have significantly contributed to this unenviable record.

It has been estimated that invasive animals, in particular European rabbits, wild dogs (*Canis lupus familiaris*), red foxes, feral pigs (*Sus scrofa*), and feral cats, cost Australia at least AUS$720 million annually through environmental, economic, and social damage (McLeod 2004). Furthermore, controlling feral animals costs governments and landholders more than AUS$60 million a year, with an additional AUS$20 million spent annually on research to find better methods of management.

Whether in the United States (US), Australia or New Zealand (NZ), all countries that are heavily impacted by invasive species, development of invasive animal management products is generally undertaken for one of four reasons: (1) managing an invasive species population through fertility or lethal means; (2) reducing the impact of introduced predators on livestock and endangered species; (3) preventing damage to infrastructure, fields and crops by herbivores, birds, and burrowing pests; (4) reducing the risk of disease transmission among invasive species, domestic animals, and humans, or (5) detecting and preventing the establishment d/or spread of new invasive species. Such products are commonly based on managing the invasive species populations through fertility control, lethal means, or exclusion.

Most invasive mammals occur in multiple countries and, therefore, invasive animal management products should have multiple or global markets. Table 1 details the continents and countries that identify the mammals listed as invasive in the Global Invasive Species Programme's *100 of the World's Worst Invasive Alien Species*. As can be seen, the brushtail possum (*Trichosurus vulpecula*) in NZ is a rare exception to the rule that most invasive species occur in multiple locations throughout the world.

HARMONISATION

Harmonisation is defined by Wikipedia as the process in international law by which different states adopt the same laws (en.wikipedia.org/wiki/Harmonisation). Many forms of global harmonisation are essential and well underway. Relevant examples include the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) and the United Nations Economic Commission Globally Harmonized System of Classification and Labeling of Chemicals. In relation to the second, Governments endorsed Chapter 19 of Agenda 21 at the United Nations Conference on Environment and Development in 1992 as the international program of action for developing and implementing national chemical safety and management programs.

Table 1. Global distribution of the mammal species listed within the *100 of the World's Worst Invasive Alien Species list*. Data collated from the Global Invasive Species Database (www.issg.org/database/welcome).

Common name	Scientific name	Continents and countries in which they are considered invasive
Brushtail possum	*Trichosurus vulpecula*	New Zealand
European rabbit	*Oryctolagus cuniculus*	Australia, Canada, Chile, France, Kiribati, Mauritius, Mexico, New Zealand, North America
Feral cat	*Felis catus*	All continents, except Antarctica, and many islands
Feral goat	*Capra hircus*	Americas, Australia, Europe
Feral pig	*Sus scrofa*	All continents, besides Antarctica
Grey squirrel	*Sciurus carolinensis*	Canada, Ireland, Italy, South Africa, United Kingdom
House mouse	*Mus musculus*	All continents, except Antarctica, and many islands
Indian mongoose	*Herpestes javanicus*	Americas, Asia, South Pacific islands
Long-tailed macaque	*Macaca fascicularis*	Hong Kong, Indonesia, Mauritius, Palau
Nutria	*Myocastor coypus*	North America, Europe, Africa
Red deer	*Cervus elaphus*	Australia, Israel, New Zealand, South America, Virgin Islands
Red fox	*Vulpes vulpes*	Australia, Canada, Mexico, United Kingdom, North America
Ship rat	*Rattus rattus*	All continents, except Antarctica, and many islands
Stoat	*Mustela erminea*	North America, Europe, Asia, New Zealand

Chapter 19 program areas include: (1) expanding and accelerating international assessment of chemicals risk, (2) harmonisation of classification and labeling of chemicals, and (3) information exchange on toxic chemicals and chemicals risks, among other areas (www.nicnas.gov.au/International/Agenda_21.asp). As such, harmonisation is already occurring in the international classification of toxins. Of particular interest to the authors is the harmonisation of data requirements for registering toxins or other actives for the purpose of invasive species management.

In relation to invasive species management products the potential benefits of global harmonisation are: (1) standardized regulatory information processing worldwide, (2) reduced costs of product development, and, in turn, of products, (3) potential for regulatory burden sharing, (4) completion of studies that may not be appropriate to or affordable in other countries, (5) accelerated time-to-market, (6) reduced duplication and additional use of animals/resources, and (7) achieve economies of scale that make product development and markets viable.
The authors do, however, recognize that although generally a positive step, international harmonisation does need to be balanced with national needs and concerns.

The cost of developing and registering new invasive animal products is only envisaged to become more expensive and complex. Examples of product development and registration costs in Australia range from AUS$500,000 and 4 years for the relatively simple PIGOUT® feral pig bait to potentially AUS$5M and 5+ years for the more complex registration (in preparation) of para-aminopropriophenone, a predacide currently under development at the IACRC (see below). Additionally, good scientific research is no guarantee of success, as shown with the research into virally-vectored immuno-contraception for rabbits, foxes and house mice (*Mus domesticus*), which cost more than AUS$10M over 12 years, but resulted in no registered products (Williams 1997). A similar large-scale genetic fertility modification project (known as daughterless technology) is currently underway with European carp (*Cyprinus carpio*) in Australia (Thresher and Bax 2003, Grewe et al. 2005), with the project estimated to cost more than AUS$10M over 10 years, albeit with the prospect of success still achievable. In addition, vertebrate pesticide registrations are actively being lost due to the cost and data requirements in maintaining them (Jacobs 1992).

Registering vertebrate pesticides already has commonalities worldwide. Whether through the Australian Pesticide and Veterinary Medicine Authority (APVMA), the US Environmental Protection Agency (EPA), or the NZ Environmental Risk Management Authority (NZ ERMA), data requirements for registering a new active or re-registering an existing active are somewhat analogous. Table 2 documents the respective registration requirement outlines for the APVMA and EPA. Although similar, data requirements by the EPA are possibly more extensive, and this potentially is a serious drawback to direct adoption of the EPA model in the event of product registration harmonisation.

PRODUCT DEVELOPMENT

The initial IACRC product pipeline is detailed in Table 3 and it indicates the most promising products currently under development at the IACRC. The list is not exhaustive, and numerous other products for canids, feral pigs, cane toads (*Bufo marinus*) and European carp are in various stages of development. Below are some further details on each product.

Feral Pig Bait, New Toxin and Delivery Systems

Development of PIGOUT®, a non-meat-based omnivore bait designed to be attractive to feral pigs but not to herbivores or carnivores, began in 2004 through the support of Meat and Livestock Australia Ltd. and the National Feral Animal Control Program (NFACP). The manufactured bait had to be highly attractive to pigs, cheap, target-specific and easy to use. Trials have been conducted around Australia, and have achieved 78 ± 4% (S.E., n=9 sites) population or activity reduction with ground baiting and 62 ± 9% (S.E., n=4 sites) biomarked or activity reduction with aerial baiting (see Cowled et al. 2006a for trial example). High target-specificity has been achieved in all Australian trials (Cowled et al. 2006b). A registration package was submitted to the APVMA in August 2006 and the product is expected to be registered shortly. PIGOUT® has also been investigated for its ability to deliver simulated vaccines both in Australia (Cowled et al. In Press) and in the US (Campbell et al. 2006, Campbell and Long 2007). Further trials have been conducted in NZ and the United Kingdom (UK).

Toxic PIGOUT® baits currently contain sodium monofluoroacetate (1080). Although 1080 is lethal to feral pigs, large doses are required and its

Table 2. Registration dossier requirements for a new active by the Australian Pesticide and Veterinary Medicine Authority (from www.apvma.gov.au/industry/MORAG.shtml) and the EPA (from www.epa.gov/pesticides/regulating/data.htm).

APVMA New Active Registration Dossiers	EPA Pesticide Data Requirements
Part 1 Application overview	**Types of Studies:**
	Residue chemistry
Part 2 Chemistry and manufacture	Environmental fate
	Degradation studies
Part 3 Toxicology	Metabolism studies
	Mobility studies
Part 4 Metabolism and kinetics	Dissipation studies
	Accumulation studies
Part 5A Residues	
	Hazard to Humans and Domestic Animals:
Part 5B Overseas trade aspects of residues in food commodities	Acute studies
	Subchronic studies
	Chronic studies
Part 6 Occupational health and safety	Teratogenicity and reproduction studies
	Mutagenicity studies
Part 7 Environment	Metabolism studies
	Reentry protection
Part 8 Efficacy and safety	Pesticide spray drift evaluation
Part 9 Other trade aspects	**Hazard to Nontarget Organisms:**
	Short-term studies
Part 10 Special data	Long-term and field studies
	Product performance

Table 3. The Invasive Animals Cooperative Research Centre (IACRC) product pipeline by year. The table lists some of the key products currently being developed with the IACRC, all of which are potentially suitable for global markets.

Product	2006	2007	2008	2009	2010	2011	2012
PIGOUT- feral pig bait*	■	■					
Freeze-dried calici-virus bait for rabbits	■	■					
High output carbon monoxide fumigator for burrowing animals*	■	■					
PAPP fox bait	■	■	■				
PAPP wild dog bait*	■	■	■	■			
Attractants/tools for feral pig management		■	■	■	■		
A new humane feral pig toxin		■	■	■	■		
Daughterless carp and other carp control tools	■	■	■	■	■	■	■

* Already trialled overseas

effect can be variable. This has lead to a search for new feral pig actives. A promising candidate has recently been found that has been shown to be a rapidly lethal and humane means of euthanizing feral pigs in gavage and bait delivery pen trials. The compound will be the subject of research, development and registration efforts over the next three years. Overseas markets, such as NZ and the US (Hawaii in particular), will be sought for HOG-GONE®, the new active contained within the PIGOUT® bait, so beneficial scales of production can be achieved.

Freeze-Dried Calici-Virus Bait

Wild European rabbits in Australia exhibited the fastest rate of spread of any colonizing mammal anywhere in the world. They now represent one of the most widely distributed and abundant mammals in Australia. Rabbit control has been greatly assisted by the release of two viruses as biological control agents, myxoma virus and rabbit hemorrhagic disease virus (RHDV) or Calici-virus. Compared to myxoma virus, RHDV is a very efficient and humane method of rabbit control, and it has had a significant impact on some (but not all) rabbit populations, e.g., a mean 92% population reduction in Victoria since its release (McPhee et al. 2001). Until recently, the virus was spread following the injection of a small number of captured and re-released rabbits. However, approval has now been obtained from APVMA for the spread of RHDV by the oral route on treated carrots or grain. Despite being a step in the right direction, there have been unforeseen difficulties in dealing with the frozen viral suspension that directly impact on the efficient and effective deployment of RHDV in the field and, therefore, the efficacy of this bio-control. The greatest impediment to the widespread distribution of the stock RHDV virus is the need to store and distribute the finished product at ultra-low temperatures. As a result of changes to transport regulations, shipments containing dry ice are classified as “Dangerous Goods” and their movement, especially by airfreight, is exceedingly difficult. The result is increased cost, in addition to failure of some shipments.

The current project, supported by the NFACP, aims to remove these impediments and difficulties in producing, storing, shipping and handling the viral suspension by producing a stock of virus in a freeze-dried form. Therefore, this project has three complementary aims. Firstly, to dramatically improve the ease and convenience of manufacturing and storing a shelf-stable RHDV product that will reduce the costs of goods. Secondly, to increase the shelf-life and simplify the storage and shipping conditions of the RHDV product that will reduce the cost of goods to the end-user. Thirdly, to produce a highly practical, shelf-stable RHDV product that will increase market uptake and responsible use within an integrated rabbit control strategy that will enhance the overall effectiveness of RHDV as a bio-control agent and prolong its effective life. The end product will be suitable for export to other countries or islands wanting to manage or eradicate European rabbits.

High Output Carbon Monoxide Fumigator

The control of rabbits has historically been achieved by a number of methods, with warren fumigation being one method that is considered to be a simple and effective technique, as well as one that can be readily undertaken by landholders. Pressure fumigation is regarded as being more efficient than the static method, due to its greater ability to force gas throughout the warren with all openings found and sealed. However, in recent times, there have been Occupational Health and Safety issues concerning the use of the currently used fumigant (chloropicrin) with pressure fumigators that have halted the use of this technique by landholders in New South Wales, Australia. Also, animal welfare concerns have arisen over the use of chloropicrin in general. Carbon monoxide (CO) has been proposed as the most humane gas to use for fumigation purposes, though to date there has been no successful means developed to deliver sufficient concentrations and purity of this gas into a warren system. The Victorian Department of Primary Industries, through NFACP support, has been developing a highly portable fumigator which can be carried by a single person (Gigliotti et al. 2001). Carbon monoxide fumigation is currently registered in Australia, NZ, the US, and the UK. The prototype high output, fan-forced CO pressure fumigator is particularly suitable for large and complex burrows. Rabbits in Australia and NZ, pocket gophers in the US (Fagerstone 1997) and European badgers (*Meles meles*) in the UK all occupy dwellings that potentially require pressure fumigation if CO levels are to increase rapidly enough to cause the quick and humane death of burrow occupants.

Para-aminopropriophenone

Para-aminopropriophenone (PAPP) was initially investigated as an alternative predacide to 1080 by the US Department of Agriculture (USDA) 25 years ago (Savarie et al. 1983). Research into PAPP was discontinued following re-approval of 1080 use in Livestock Protection Collars. The mode of action for PAPP is the conversion of haemoglobin to methaemoglobin, the latter of which cannot carry oxygen. A rapid and humane death results from a lack of oxygen to the brain and cardiac muscles. The average time to death for bait-delivered PAPP is approximately one hour for feral cats and foxes and 2 hours for wild dogs (D. Dall, personal observation). Low levels of methaemoglobin reductase in eutherian carnivores may be a factor that is responsible for their high sensitivity (compared to other mammals) to the compound (Srivastava et al. 2002). PAPP is currently being investigated for wild dogs and foxes (Fleming et al. 2006, Lapidge et al. 2006) and feral cats (Fisher et al. 2001) in Australia, and stoats (*Mustela erminea*), ferrets (*M. putorius*), and feral cats in NZ (Fisher et al. 2005, Murphy et al. 2005, Fisher and O'Conner 2007). The canid component of the project is sponsored by Australian Wool Innovation Ltd. (AWI), and it is hoped that a fox PAPP bait registration will be submitted late in 2007 with a wild dog PAPP registration to follow thereafter. The active is suitable for coyotes (*Canis latrans*) in the US and other pest or invasive eutherian carnivores requiring humane lethal control.

'Daughterless' Technology

European carp are often referred to as the 'rats of the river' in Australia. The species is widespread throughout the Murray-Darling Basin, Australia's most extensive and important water source, and causes extensive environmental problems in relation to water quality and native fish survival. Genetic technologies offer potential to manage carp populations. This has lead to the study of sex-specific apoptosis in carp and other model species for achieving 'daughterless' fish (Grewe et al. 2005). The Commonwealth Scientific and Industrial Research Organization (CSIRO) commenced research into daughterless carp in 2003 with the backing of the Murray-Darling Basin Commission and the Pest Animal Control CRC (IACRC's forerunner). Daughterless technology involves an engineered genetic construct using homologous species-derived genes that are inheritable and that bias offspring sex ratios towards males. Models indicate that replacing 5% of wild type recruits each year with daughterless carriers would lead to a significant decrease in population levels by 2020 and near extinction by 2030 (Thresher and Bax 2003). The technique is also being investigated for cane toads in Australia, and is potentially useful for other invasive fish or amphibians worldwide.

Attractants and Pheromones

Numerous attractants, pheromones, and repellents are currently being investigated within the IACRC, Pestat P/L, and research partners for commercial or environmental applications. With AWI's assistance, the first product to be commercialized by Pestat P/L has been FeralMone®, a highly attractive dog and fox lure that is based on a proprietary formulation of synthetic fermented egg (Bullard et al. 1978). Field trials in Australia showed that FeralMone® significantly increased site (bait or trap) visitation and bait take (Hunt et al. In Press). Other lures are currently being investigated for feral pigs and carp (attractants), cane toads (attractants and repellants) and kangaroos (*Macropus* spp., repellents). It is likely that each would be useful in multiple countries around the world for various wildlife management applications. Ideally, different countries and markets need to be identified early in this process so appropriate packaging and labeling can be developed.

USDA Products Currently Being Investigated in Australia

While Australia is one of the regions at the forefront of invasive species management product development (perhaps out of necessity), we also constantly look to our international research partners in NZ (Connovation Ltd., NZ Department of Conservation, and Landcare Research), the US (USDA National Wildlife Research Centre and University of Minnesota) and the UK (Central Science Laboratory and University of York) for further advances in the field. Invasive species products previously developed by our partners (or other organisations) that are currently under investigation in Australia, besides those previously mentioned, include the GnRH GonaCon™ immunocontraceptive vaccine (Fagerstone et al. 2006) and the SenesTech Inc. accelerated ovarian senescence product for reducing the fertility of macropods and other invasive species. This research is being undertaken within the IACRC. Pestat P/L, as a separate entity, is also investigating

DRC-1339 (aka Starlicide™) for European starling (*Sturnus vulgaris*) control (Lapidge et al. 2005); M-44 mechanical ejectors for red fox and wild dog control (Marks et al. 2003, 2004); the Coyote Operative Lure Device (CLOD) for wild dog and fox control (Berentsen et al. 2006); and egg oiling for bird control (Martin et al. 2007). Furthermore, the IACRC is interested in the cocoa- and coffee-derived methylxanthines for canid control in the event that a further predacide is required in addition to PAPP (Fagerstone et al. 2004, Johnston 2005). All of the products will require preparation of extensive registration packages before they can be used in Australia. For the most part, such registration packages exist or are in preparation overseas, and it is hoped that future harmonisation between the relevant national pesticide registration organizations will facilitate product registration by the APVMA in Australia.

DISCUSSION

Product development in the field of invasive species management is currently evolving at a rapid pace never seen before. As governments and industry begin to appreciate the scale of the ever-increasing invasive animal problem, a growing number of biotechnology-based start-up companies are jostling to establish positions in what are, to a degree at least, niche markets. Despite this activity, it is likely that the role of product development will heavily rest with governments or semi-government organizations working with industry partners (the basis of the Cooperative Research Centres in Australia). The high cost of product development and registration, the small scale on which most vertebrate pesticides are used, together with the diminutive associated profit margins are likely to demand this for the foreseeable future. We suggest that the most effective way of reducing product development costs, times to availability, and regulatory burdens is through global harmonisation of invasive species management products. As outlined in this paper, we are now heading in the right direction. International efforts are currently being coordinated on wildlife fertility control research. Development of the new predacide PAPP is an ongoing collaboration between Australia, NZ and the US. PIGOUT® feral pig baits have undergone extensive testing in Australia, the US, the UK, and NZ, and the CO pressure fumigator has also been tested in multiple countries. The question we pose here is, "Are we doing all we can to facilitate product registration harmonisation where appropriate and possible?" Self-evidently, this must involve obtaining data for registrations that meet international regulatory standards, and also ensuring that any unique information required by specific international regulators is obtained or at least highlighted.

CONCLUSION

Invasive species are a global problem and global solutions are required. Effective international collaboration is essential, both between researchers and government regulatory agencies alike. This, of course, must be done with appropriate sensitivity to intellectual property ownership and appropriate catering for commercial participants to ensure private investment in the field of invasive species management continues to strengthen. Ideally, a formal agreement is required between international regulatory agencies, such as the APVMA, US EPA, and NZ ERMA, before this process can occur, as has transpired between governments in relation to chemical classification and labeling. We would also suggest that a Global Invasive Species Management Product Research Register would be particularly constructive, so researchers, product developers, private companies and governments can readily assess efforts that have already been made towards developing and registering particular products so as to avoid unnecessary duplication of effort, cost, and use of animals for research purposes.

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