Science delivering to regulators

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Abstract Regulations are a part of life but who writes them, what is the basis on which they are written and when the regulations get it wrong, whose fault is it? Is it those who wrote the regulations, those enforcing the regulations, those being regulated or the science underpinning the regulations? In seeking answers to these questions, this paper explores the regulatory process and the contribution of science. It takes as examples the role of the Australian Pesticides and Veterinary Medicines Authority (APVMA) in regulating veterinary products, of the Security Sensitive Biological Agents regulations in managing the risks from specific pathogens, the Quarantine Act regulations as applied to containment facilities and the development of welfare standards. By dealing with products, pathogens, places and “pets” it provides a broad oversight of how regulations have been developed and applied from different perspectives and highlights the differing roles that science and research play both in developing policy and regulations. What is clear is that in the presence of good science it is usually possible to develop sound and defensible regulations e.g. those managed by APVMA, but when there is a lack of

science to underpin the regulations, problems can arise e.g. in the case of animal welfare.

Keywords Regulations and science · Policy and science · Research and regulation

1 Introduction

During the past year the agricultural press in Australia has been somewhat critical of the plethora of policies and regulations that surrounds agricultural practice and particularly livestock production. Headlines such as “Regulators show no compassion for our farmers” (Anon 2013) were typical of the types of comments being received. The newly appointed Coalition Government in Australia has vowed to cut regulation and “red tape” profoundly in the coming months. This paper explores why we have regulations and examines a number of contrasting examples of the development and application of regulations in different agricultural areas. It then uses these examples to comment on the process and outcomes of our current regulatory environment for agriculture.

2 Regulations

A regulation is a written instrument containing rules having the force of law. There are many types of regulations including those that protect us from ourselves and the things we use, those that facilitate how we work together and how we trade, those that protect our fauna and our flora and those that protect our natural and built environment. There are

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many reasons for having such regulations including protecting us, our flora and fauna and our environment, ensuring that the products available to us are safe and that the world we live in is as safe as it can be. We need to ensure that the things we use do what they are meant to and do so in a way that ensures quality and fitness for purpose. We need to make sure that we receive value from our investments and that we are protected from malpractice in industry. In a nutshell, regulations exist to ensure fairness, openness and equality.¹

Science and research should contribute at all stages to the regulatory process. Most government policy has an underpinning basis of good science and in drafting the regulations that underpin the policy, it is crucial to ensure that they themselves are based on sound science, that they inherently make sense and that they have processes for compliance monitoring e.g. are enforceable.

In implementing and applying the regulations, data will invariably be required whether it is for product registration, for measuring adverse reactions or for monitoring use. The application of good science and acceptable methodologies will be essential if this data is to be of any value.

Similarly, science will underpin the review and amendment of regulation and process for oversight and evaluation. It is fundamental therefore that the regulator appropriately uses science and research findings at all stages of the regulator process.

3 Four distinct examples of agricultural regulation

Whilst the framework described above provides a succinct summary of the role and use of regulation, only by examining the process in detail can similarities and differences be properly identified and examined. Four examples have been chosen that highlight these issues:

- APVMA—the regulation of “products” (Australian Pesticides and Veterinary Medicines Authority)
- SSBA/OGTR—the regulation of “pathogens” (Security Sensitive Biological Agents; Office of the Gene Regulator)
- BA—the regulation of “places” (Biosecurity Australia—Quarantine Act dealing with the regulation of quarantine facilities e.g. AQIS as was)

- AAWS—the regulations of “pets” (Australian Animal Welfare Strategy)

3.1 The Australian Pesticides and Veterinary Medicines Authority (APVMA)

The APVMA role is that of an industry regulator, and it is the Australian Government statutory authority for the registration of agricultural and veterinary products that companies may wish to sell in the Australian marketplace. Anyone wishing to place such a product on the market place must have it approved by APVMA and this is enforceable by Australian law.²

Applications are assessed using the expertise of the APVMAs scientific staff and drawing on the technical knowledge of other relevant scientific organizations including Commonwealth Government departments and State agricultural departments, CSIRO, universities and other specialized agricultural research institutes. The underlying principle is one of a strongly science-based process throughout, with the use of applied and directed research to fill in knowledge gaps. APVMA argues that they will make consistent and predictable evidence-based decisions founded on sound science and research.

The APVMA delivers regulatory activities to protect the health and safety of people, animals and crops, the environment and trade. Although the role of the APVMA is to independently evaluate the safety of pesticides and veterinary medicines it also takes on the role of evaluating performance or efficacy. This is in strong contrast to the Therapeutics Good Authority (TGA) that evaluates human products, where the focus is primarily on safety. Thus all APVMA registered products must be shown to *work* and be *safe*. This would seem to meet a fundamental tenet of regulation.

To achieve this, the APVMA seeks a dossier of product information as a basis for registration. Science-based, this data is prescribed in detail and format that ensures consistency and transparency to the process of product evaluation. From the outset of the process, a constant dialogue between the regulator and the scientists involved in product registration ensure the right data is provided and any additional data requirements become known in a timely manner. As mentioned above, the process involves both safety and efficacy data (the product is both safe and works).

¹ <http://www.daff.gov.au/agriculture-food/biotechnology/framework>.

² <http://www.daff.gov.au/agriculture-food/ag-vet-chemicals>.

On the surface therefore, this process should be ideal in ensuring that the right products are registered for use in the market place, that they are both safe and efficacious and that they are in a transparent and regulated environment.

Yet any discussion with a farmer or agricultural based industry representative will quickly reveal discontent with what they see as a totally over regulated and bureaucratic environment in which they must operate (National Farmers Foundation 2012). It is not the process for product registration that is at fault but regulations surrounding the use of such products, that seem to take into account a range of poorly supported environmental and biodiversity issues. Whether the issue is one of lack of data, or poor communication is an area of considerable contention and one the current Government intends to deregulate.

3.2 Security Sensitive Biological Agents (SSBA)

This is a relatively new area of regulation and provides an insight into both the development and application of new regulation.

The anthrax outbreaks in the USA in 2001 resulted in a range of regulatory changes throughout the world to deal with the risk from biological weapons. In 2001 the USA introduced the US Patriot Act, whilst the UK introduced the Anti-terrorism Crime and Security Act. Australia was slower to follow with the Act only really coming into law in 2008. This was preceded by an intense period of consultation with the science community throughout Australia in order to ensure an appropriate and workable set of regulations to manage the risk from biological weapons.

The starting point is a list of biological agents derived from security intelligence that considers what terrorists might be interested in using, what would be the impact to Australia if they were used and how easy it is to acquire, grow and deliver such agents. Australia has two lists (see below) of SSBA agents, tier one being the more serious risk agents which are subject to a set of more stringent regulations than those applied to tier two.³

Tier 1 organisms

- *Bacillus anthracis* (Anthrax-virulent strains)
- *Ebola virus*
- *Foot-and-mouth disease virus*

- Highly pathogenic influenza virus, infecting humans
- *Marburg virus*
- *Rinderpest virus*
- *SARS coronavirus*
- *Variola virus* (Smallpox)
- *Yersinia pestis* (Plague)

Tier 2 organisms

- *African swine fever virus*
- *Capripox virus* (*Sheep pox virus* and *Goat pox virus*)
- *Classical swine fever virus*
- *Clostridium botulinum* (Botulism; toxin-producing strains)
- *Francisella tularensis* (Tularaemia)
- *Lumpy skin disease virus*
- *Peste-des-petits-ruminants virus*
- *Salmonella* Typhi (Typhoid)
- *Vibrio cholerae* (Cholera) (serotypes O1 and O139)
- *Yellow fever virus* (non-vaccine strains)

The NHS Act of 2008 provides the framework in which to operate the SSBA regulatory scheme. This scheme works in conjunction with SSBA standards to provide the operational detail and the Act allows for fines and imprisonment for breaches of these regulations. The SSBA standards and regulations relate to personnel policies and procedures, physical security and access controls, information and data management, transport, inactivation and decontamination and the overall SSBA management system.

It should be noted that prior to the introduction of these new regulations into the Australian science world, there had been an intense period of consultation with scientists, researchers, managers and administrators in order to ensure that the regulations were science based, particularly in areas dealing with pathogen handling and storage. Notably however, the list of agents was produced behind “closed doors” and whilst obviously risk based, the set of criteria remained secret. There is currently a process of review and re-assessment of these two lists but again without reference to the wider scientific community. One underlying feeling was that the regulations and standards were based on “what would work” rather than a genuine scientific assessment of risk. The obvious outcome of these new regulations are that considerably less institutes and people now handle Tier One, and to a lesser extent, Tier Two agents and that the whole process of working with SSBA is costly and time consuming.

This is a set of regulations based around reducing the risk of a bioterrorist event in Australia. It has had

³ <http://www.health.gov.au/ssba>.

an enormous impact for those wishing to undertake research or carry out diagnostic work on those pathogens in both Tier One and Two. For the most part this has resulted in a considerable increase in the cost of doing such work and a major reduction in the number of scientists now engaged in such work. But has it quantifiably reduced the likelihood of a bioterrorist attack by restricting access to, and use of potential bio-weapons? It is unlikely that such data would be made available, even if it existed but it does make the impost of these regulations on the science communities somewhat more difficult to accept.

3.3 Biosecurity Australia quarantine facility regulations

The Quarantine Act of the Australian Government has been in existence for many years and it has been recognised for some time that it requires a complete rewrite. The current Government is undertaking this at present in the guise of a new Biosecurity Act.⁴ The current Act though covers all aspects of quarantine including those regulations relating to quarantine facilities. These are based on prescribed regulations and govern all aspects of the build and operation of a quarantine premises. Many of the regulations are outdated and there are many new design and engineering features that now relate to the operation of Pathogen Containment level Three and Four agents (PC3/PC4). Interpretation of the outdated regulations by the regulatory body (Australian Quarantine Inspection Service, AQIS until recently) was undertaken by consultant engineers although the process for supporting decisions seemed often to lack quantifiable data and underpinning science.

Some specific examples of this include:

- the move away from continuous flow treatment of liquid waste to one based purely on batch treatment. Continuous flow is the process used by the milk industry for pasteurisation of milk and has been demonstrated as efficacious for many years. For material with relatively low contamination such as shower water it is relatively inexpensive and would be considered by many as managing the risks associated with such material. However it is now largely unacceptable to the regulator for waste treatment in PC3 and PC4 facilities. There is currently little science to support this decision.

- Showering. It is historically assumed that showering out from a PC3 or PC4 facility is a science proved necessity. This is not the case. In fact very little data exists to demonstrate the utility of showering out of such facilities in terms of reducing pathogen escape. There may be value in other terms but for reducing the risk of a pathogen escape, the data does not exist. Yet it is a firm regulation for all such facilities. It should be noted that a similar lack of data supports the use of chemical disinfectants for decontamination of PC4 suits although this would perhaps be a non-debateable requirement.
- Discontinuation of the use of formaldehyde. It is now widely accepted that the use of formaldehyde must be discontinued as a room disinfectant even though it has proved safe and effective for this use over many years. The Group of High-Containment Facility Directors pleaded three years ago for the continued use of this disinfectant for room decontamination but to no avail and the regulator has all but banned the use of formaldehyde as it classified by the International Agency for Research on Cancer as a carcinogen and is a known allergen and irritant. There is however no real scientific data on the negative impacts of formaldehyde used for the purpose of room disinfection where adequate health and safety regulations exists to manage the risks to personnel.
- Use of fly screens in PC3 and PC4 facilities. In high containment facilities, the input air is normally filtered through a high efficiency particulate air (HEPA) filter to remove any virus (or larger pathogen) from entering such buildings. This process is repeated with the air leaving the building. Current regulations being applied by the Office of Gene Regulator (OGTR) seem to insist that over and above this, a fly screen must be placed inside of the HEPA filter to prevent flies entering such facilities. Placing such a filter on the outside of the HEPA filter might be valuable in protecting such expensive filters but the regulation demands it be on the inside. It seems absurd to consider that a filter designed to prevent a virus entering the facility would allow a fly through.

3.4 Development of Animal Welfare Standards

Australian Animal Welfare Strategy (AAWS) commissioned Animal Health Australia to facilitate the development of nationally consistent standards and

⁴ <http://www.daff.gov.au/biosecurity>.

guidelines for livestock with the overall objective of improving welfare outcomes but in ways that were as practical and affordable for industry as possible (AHA 2013).

It was accepted from the outset that Standards will be a legal requirement and will use the word “MUST”; it was also considered critical that there was national consistency in legislation to enable industry to work across State boundaries. It was also accepted that whilst reinforcing standards in Australia this would also serve to underpin access to overseas markets.

In developing animal welfare standards it was appreciated that such standards must be desirable for livestock welfare, feasible for industry and government to implement and useful in the context of a livestock-welfare regulatory framework.

Critical to the whole process is the lack of science to determine “acceptable welfare” in animals. There are little realistic quantifiable (or even qualitative) measures in animals and moral and ethical considerations blur what science we do have. Objective science is required and in general science has let the regulator down in this area. What is acceptable to the public is a major issue and in the political environment that the regulator often sits, political expediency and public support outweigh what science is available; or at least in the absence of scientific evidence will be used to develop the regulations or to set standards (Boissy et al. 2007).

As an example, the regulations concerning the use of cages for egg-laying hens were agreed in Australia just a couple of years ago. The industry then made huge changes, at considerable cost, to meet these regulations. Yet only weeks ago, the largest egg retailer in Australia made the decision to only sell eggs from free-range birds. This has placed many egg producers in a precarious financial position in still paying off debts to meet regulations that the current market environment has made pointless.

4 Conclusions

It is crucial that wherever possible science is used to underpin both the development and application of regulations. However many non-science imperatives impinge on the development and use of regulations and there are often valid reasons for paying heed to these requirements.

It should be noted that 75 % of changes to regulations are related to technology advancements. It is

a continually moving “feast” and it is not easy for regulations to keep up with our every changing environment. Beyond this, consumer perceptions and society expectations continually evolve and change. Where science cannot provide answers, or is not applicable, invariably debate and discontentment exists. And in some situations, even when science can provide solutions there is still debate and discontent. Whilst we can argue that inadequate resources are allocated to fund research to assist the development of regulations and their subsequent application, it is not just about science but about dealing with uncertainty in an ever increasing complex world.

All four cases presented accept and defend the need for regulations. But each case illustrates a different issue around the development and use of regulations. In the case of agricultural chemicals it is primarily related to the burden on farms imposed by the need to adhere to the regulations, in the case of security-sensitive pathogens it is about appreciating the real risk that is being tackled and the likelihood of a bioweapon attack. In the case of quarantine facility regulations, it is more about fitness for purpose of the regulations themselves whilst in the case of animal welfare it is a lack of quantifiable basis for measuring welfare outcomes in animals that provokes debate.

In conclusion, the regulations are about dealing with risk—and science is in theory good at this. But we clearly need to be certain about whose risk we are trying to address, what risk is acceptable and how well we have communicated the value that regulations will bring to reducing that risk.

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