Review of the Agvet Chemicals Regulatory System - Issues Paper

RSPCA Submission

27 August 2020

This submission has been prepared by RSPCA Australia with input from state-based RSPCA member societies.

A) General comments

We are pleased to see this substantial review being undertaken and would encourage a review of any reforms resulting from this process be undertaken within two years of major changes being implemented. We are also pleased to note that the Panel is engaging with a broader range of stakeholders to those who provided input into the Issues Paper, as this will greatly assist in understanding the issues from all perspectives.

This submission contains responses to specific questions posed in the Issues Paper and raises additional issues.

i) Current system

A general response is provided below for the areas of the current system that the Panel considered worthy of retaining as is.

Area	RSPCA response
Independence of the national regulator with no political interference in its scientific decision making	Support
Scientific rigour and technical proficiency of the APVMA, leading it to be a world class regulator	Support
Centralisation of the supply side regulation of agvet chemicals	Support
Importance of the criterion for assessing trade impacts to protect our agricultural exports	Support
Use of a risk-based approach to chemical assessment	Support
Need to maintain or expand the current minor use grants program to increase farmers' access to chemical uses	Provisional support on basis that sufficient risk mitigation is undertaken

Comments regarding specific areas relating to animal welfare to be refined and/or improved are contained in the following section.

ii) Animal welfare

The RSPCA strongly supports the recognition of the importance of animal welfare in the Issues Paper, specifically regarding the following statements:

Proposed primary purpose statement (p13):
'The panel is therefore of the view that protecting animal welfare into the future should be a key focus of the agvet chemicals regulatory system. Considering this, the panel is proposing that protecting animal welfare should be the third and final objective in the hierarchy.'

Trends - Consumer market expectations and authenticity (p7):
'Animal welfare and ensuring animals are treated humanely in food production will continue to grow as a consideration in domestic and export markets (Futureye 2018).'

Trends - Social Licence (p8):
'Community pressure will also likely strengthen around animal welfare concerns. The future regulatory system needs to acknowledge and accommodate the community's changing expectations in relation to responsible animal production.'

The RSPCA believes that considering animal welfare in relation to the regulation of agvet chemicals is of critical importance for the following reasons:

- Increasing community expectations regarding how animals are treated and managed.
- Increasing consumer expectations regarding the welfare of production animals used for products people use and/or consume; this also has implications for trade and export products (e.g. mulesed wool).
- Increasing understanding of the negative impacts of chemical toxins used in vertebrate animal control programs and the need to develop and use humane methods.
- Increasing recognition regarding the animal welfare impacts of disease-causing biological control agents for vertebrate animal control.
- Increasing concerns regarding the use of chemicals, particularly antimicrobials, to address conditions and animal welfare risks inherent in intensive animal production systems such as early weaning, overcrowding, poor hygiene and limited opportunities to express appropriate behaviours leading to stress. The continued reliance upon the use of these products favours the development of antimicrobial resistance and does not address the underlying poor management practices, which may result in compromised welfare.
- Increasing focus on the need to use pain relief products to prevent and minimise pain associated with surgical husbandry procedures and the need for appropriate regulation of the use and access to these products (see '2. State of the system' for more information).

Animal welfare is at risk if animals;

- do not receive appropriate veterinary chemical treatment to treat illness, injury or other conditions which may compromise welfare;

- do not receive appropriate prophylactics including vaccinations and anti-parasitic treatments;

- receive treatment that is ineffective thereby not alleviating pain or suffering;

- are exposed to inhumane toxins which cause pain and distress, whether they be target or non-target animals;

- are exposed to biological control agents which cause painful and debilitating disease (e.g. Rabbit Haemorraghic Disease Virus, Koi herpesvirus) or

- are not provided with appropriate analgesics to prevent or minimize pain associated with surgical husbandry procedures such as castration, dehorning/disbudding, mulesing, tail docking etc.

There is increasing community concern and expectations regarding the treatment of all animals including vertebrate pest species. In the past, little scrutiny has been given to the animal welfare impacts of vertebrate pest control methods (Littin et al 2004). Fortunately, over the past decade, there has been a greater focus on the animal welfare impacts of pest animal control methods. However, unless this translates into improved practices on the ground, progress will not be achieved. More needs to be done especially in relation to humaneness of control methods (particularly for toxic baits), competency of operators and research into more humane management options. There is also an important role for regulators who register and regulate the use of these products, particularly where significant welfare risks exist (Littin 2012). For example by restricting ways that methods are manufactured, sold or used to manage animal welfare impacts such as restricting use to approved operators. This is particularly relevant to the use of anti-coagulant products for pest rodent control.

Animal welfare outcomes could be significantly improved if a humaneness assessment of new and existing chemicals for vertebrate pest control became a mandatory requirement for registration (Humane Vertebrate Pest Control Working Group 2004; Littin et al 2004; Littin & Mellor 2005).

The RSPCA has urged the APVMA over many years to consider the inclusion of the humaneness assessment model (Sharp & Saunders 2011) as part of the registration approval process. This model is internationally recognised and provides a practical way of assessing humaneness that can be applied to any pest control method, thus allowing comparisons of animal welfare impacts of different methods.

The model matrix which is used to calculate a score for humaneness includes all five 'welfare' domains (Mellor & Reid 1994);

i. water/food deprivation;

ii. environmental challenge;

iii. disease, injury or functional impairment;

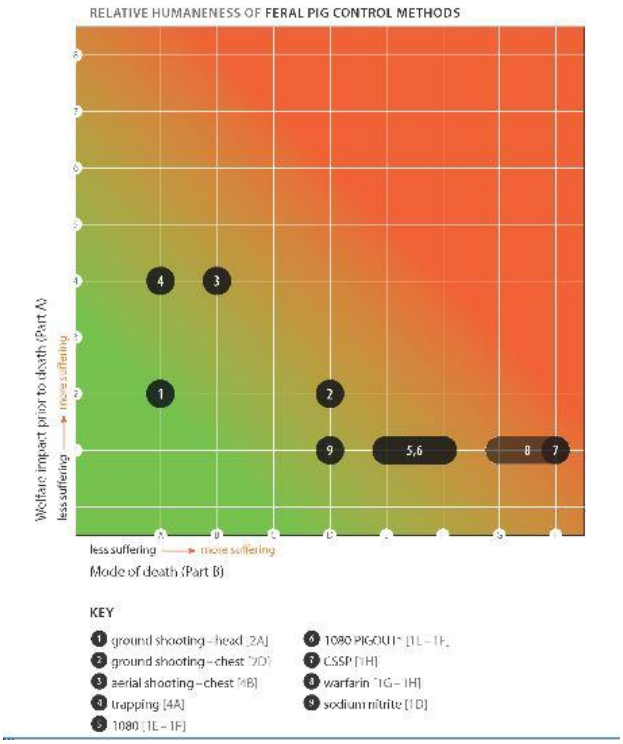
iv. behavioural or interactive restriction; and

v. impact on mental state - anxiety, fear, pain or distress;

Further details of the model are available here: http://www.pestsmart.org.au/a-model-for-assessing-the-relative-humaneness-of-pest-animalcontrol-methods/

The matrix is an invaluable resource to assist chemical users to select the most humane method available where more than one chemical is assessed. For example, four different chemicals are included for feral pig control – 1080, sodium nitrite, yellow phosphorus and warfarin. In terms of relative humaneness, sodium nitrite is the most humane with yellow phosphorous being the least humane (see Graph 1).

The relative humaneness matrix for feral pig control can be found at: https://pestsmart.org.au/toolkit-resource/feral-pig-control-methods-humaneness-matrix/



Graph 1: Relative humaneness matrix for feral pig control methods

The humaneness model website also contains worksheets for each method which shows how the humaneness scores were derived. Depending on the chemical, the worksheets may provide advice regarding the acceptance of the continued use of some chemicals on welfare grounds, especially where more humane alternatives are available. Consideration should be given to withdrawing the registration of specific products which are considered to cause severe and prolonged suffering with the relative humaneness worksheets being used to guide such decisions. For example, the worksheets for the relative humaneness assessment of warfarin and yellow phosphorous for feral pig control, state that these chemicals are considered to be inhumane as they cause extreme suffering over days. Although the worksheet notes that the use of these chemicals is being phased out in states/territories, it would be much simpler and more efficient for the national registration of products containing these chemicals to be withdrawn. It is also understood that not all states/territories have phased out the use of these chemicals. To access these worksheets visit: https://pestsmart.org.au/toolkit-resource/feral-pig-control-methods-humaneness-matrix/

B) Specific comments

1. Proposed vision

An Australian regulatory system for agvet chemicals that provides all Australian primary producers and veterinarians with timely access to a similar range of approved agvet chemicals to their overseas competitors, while preserving human, animal, plant, and environmental health.

a) Do you support the proposed vision for the agvet chemicals regulatory system and is it sufficient to meet the needs of all stakeholders?

Response: The proposed vision appears to be sufficiently succinct and comprehensive.

b) What, if any other considerations should be included in the vision?

Response: Suggest adding 'safety' after 'health' as this would encompass welfare, which considers more than just health risks. Also, would need to consider the implications of the vision statement only referring to primary producers and veterinarians, as there are other chemical users which should be included such as;

- **Pest control operators and others, including the general public who use chemicals to control vertebrate pests either for conservation purposes or in a residential setting**
- **Consumers who purchase over-the-counter products which contain compounds which require appropriate review in terms of efficacy and potential animal welfare risks**

2. State of the system

Do you agree or disagree with the future trends identified and their implications for the agvet chemicals regulatory system?

a) Are there additional implications for the regulatory system posed by the trends identified that the panel has not adequately addressed? If yes, please provide details.

Response: With regard to social trends, there is increasing concerns regarding the impact of chemicals on animal welfare. This applies to any chemical but is most relevant to toxins used for pest animal control.

With regard to farm practice, pest animal control should also be mentioned as this is an integral and increasing part of operations and for the viability of many primary producers. In addition, there should also be an acknowledgement of the increasing focus and concerns regarding the relative humaneness of different methods of pest animal control. There is limited uptake of more humane methods (including non-lethal and chemical options) and a continued reliance on 1080 which is considered inhumane and also has high non-target risks. For example, rather than reducing the use of 1080, there appears to be an increasing demand, i.e. there is a current push for national registration of 1080 for feral cat control and yet a more humane toxin, para-aminopropiophenone (PAPP) has been recently registered for use for feral cats (Curiosity®).

Another issue relates to chemical products which are used to treat animals which may cause harm. An example would be liquid nitrogen used for the procedure known as steining (applied to the breech area of lambs to destroy skin containing wrinkles to reduce the risk of flystrke) which is deemed to cause pain. It would be helpful to require a label warning on these types of products which cause pain, including advice regarding the use of an appropriate analgesic.

Furthermore, investigation must also be undertaken regarding analgesics especially topical analgesics used for painful husbandry procedures which are applied after the procedure is carried out, i.e. for mulesing, tail docking and dehorning. It is recommended that a label advice statement should be included regarding the administration of a registered analgesic prior to the procedure to minimise pain associated with the procedure.

These are important considerations to address key welfare risks associated with the use of registered chemicals.

b) Are there other trends that the panel needs to consider in designing the future system?

Response: As per a), product assessment should include relative humaneness assessment to meet increasing community concerns regarding animal welfare impacts of pest control chemicals.

3. Hierarchy of objectives

Do you support the proposed overarching primary purpose statement for the agvet chemicals regulatory system being safety and access?

a) Do you agree that the proposed hierarchy of simplified objectives provides greater clarity of their relative importance and is this supported? If not, why?

Response: Firstly, efficacy is a critical aspect and must be included in the primary purpose statement along with 'safety' and 'access'. It is suggested that all three objectives are on an equal level rather than prioritising them. Poor animal welfare outcomes can impact on trade, so placing animal welfare third does not reflect the potential inter-relationships between these objectives. Also suggest changing 'promote' to 'support' primary industry as promote may not be an appropriate role for a regulator.

b) Are there objections to removing the domestic chemical manufacturing objective? If so, what are the objections?

Response: It is unclear as to the role of the agvet regulatory framework regarding domestic chemical manufacturing but removing this could impact on animal welfare. It is understood that innovations have been derived from development and product registration work undertaken by domestic chemical companies and with the trend for larger global mergers combined with Australia's relatively small market share, it could be risky to ignore this potential contribution to assist primary producers in particular.

c) Do you agree that the current objectives for efficiency, transparency and risk-based science are more appropriately expressed as principles governing design of the system? If not, why?

Response: This seems appropriate.

d) Are there other objectives that should be considered?

Response: No comment.

4. Guiding principles

Do you support the principles proposed to guide design and reforms to the future agvet chemicals regulatory system? If not, why?

Response: The proposed principles appear to be comprehensive and to have merit.

a) How could these principles be enshrined to ensure they are met?

Response: No comment.

b) Do you have suggestions for additional principles that should be considered by the panel?

Response: No comment.

5. Risk assessment

Do you agree that the regulatory system needs to have a risk-based focus to provide for a more scientifically robust and comprehensive system? If not, why?

Response: A risk-based focus has merit but there are concerns regarding the capacity of a risk-based system to consider new information relating to risk for specific compounds, which may become available.

6. Governance structure

a) What governance structure might be best for delivering the Australian Government's responsibilities in the national regulatory system?

b) Do you see merit in a time-limited High-Level Steering Committee to drive implementation action on the regulatory reform agenda?

Response: Option 2 (Statutory body with board) appears to have most merit and it is essential that implementation of reforms is overseen by a high-level steering committee which must report at appropriate intervals on progress.

7. Control of use

Which of the three reform options outlined do you support and why?

a) Which option is likely to deliver the best chance of consistency in control of use and the greatest likelihood of success and why?

b) What risks do you foresee in implementing any of the options proposed?

Response: In terms of regulation of veterinary medicine use, veterinary prescribing rights and coordination of residue monitoring of domestic produce, national harmonisation is supported. Option 1 (Expanded applied law model) provides the best potential to achieve national consistency which is important in terms of veterinary

medicines given that many veterinarians frequently travel and work in different states/territories.

8. Shared responsibilities

Do you support the addition of co-and-self regulatory approaches to agvet chemicals management (across all levels of a product lifecycle like the Australian Packaging Covenant) to deliver more effective and efficient outcomes than direct regulation alone?

Response: Self-regulatory approaches pose significant risks and is not supported. However, a co-regulatory approach could mitigate these risks on the proviso that the system is robust, transparent and effective in identifying breaches which can be adequately enforced and penalized. The government has a responsibility to ensure chemicals are safe and effective. Relying on chemical users and the community to seek redress for failures regarding safety and efficacy can be prolonged and tortuous, may not result in a satisfactory outcome and in some cases could pose risks to trade and animal welfare.

9. Compliance and enforcement

Should detection and investigation measures be augmented to better treat the risks posed by agvet chemicals?

Response: Unable to comment specifically but do support nationally consistent tools and sufficient resources to effectively monitor compliance.

10. Chemicals to include

Do you support the proposal to remove consumer products and pool and spa chemicals, anti-fouling paints and certain over-the-counter companion animal products from the agvet chemicals regulatory system? If not, why?

a) Do the benefits of the proposed removal of these products outweigh the risks? If not, why?

b) Are the new definitions of a plant protection product and veterinary medicine supported? If not, why?

c) Do you agree that certain product uses, such as those administered by injection, warrant the direct involvement of veterinarians, separate to the controls under the poisons scheduling? What about farmers injecting sheep/cattle/pigs – vaccines etc

Response: Removal of consumer products and pool/spa chemicals, and anti-fouling products seems reasonable on the basis that another regulator has responsibility for regulating any products which have a human safety and/or environmental risk. There

are concerns regarding the removal of APVMA oversight of veterinary medicines which may have implication for animal welfare.

For example, there is increasing risks of chemical resistance of external and internal parasite treatments for both companion and farm animals which in turn reduces efficacy. Also, where there is widespread chemical resistance to specific products, this may have implications for human health, e.g. toxocara (round worm) infections.

11. Agricultural and veterinary chemicals – No comment

12. Assessment of use – No comment

13. Benefits assessment

Would a benefits test as proposed be a useful addition to the agvet chemicals regulatory system?

a) Are the benefits outlined appropriate?

b) Are there additional benefits that should be considered?

c) Should the benefits test have the two purposes proposed?

Response: A benefits assessment has merit. However, conflicts may exist. For example, one benefit cited in the Issues Paper is 'to control a pest of national significance (e.g. rabbits)'. However, the most commonly used registered toxin to achieve this is 1080, which is not considered to be humane. Similarly, the use of some disease-causing biological control agents (e.g. myxoma virus, rabbit calicivirus, koi herpesvirus) also pose serious welfare risks.

14. Chemical combinations

Is the area of chemical combinations highlighted worth exploring?

Response: This is an important area particularly in relation to control of internal parasites for both production and companion animals. To assist in investigating this area further, seeking advice from veterinary specialists is warranted.

15. Data mining

What role could data mining and intelligence use play in the regulatory system?

Response: Unsure of the role this could play but there appears to be some benefits in undertaking this, especially relating to antimicrobial use and resistance.

16. Monitoring of chemicals in produce and the environment

Do you support the need for a national domestic produce monitoring system and should it be modelled on the National Residue Survey?

a) Should data on residues in domestic produce be publicly available?

b) What should core design principles of such a system encompass?

Response: A national domestic produce monitoring system is supported with residue information being made public.

17. Monitoring of chemicals in produce and the environment – No comment

18. Communications

What information would consumers like to see more of from the national and state agvet chemicals regulators?

Response: The RSPCA recommends the inclusion of relative humaneness for chemicals used for vertebrate pest control on the basis that this will assist end users to select the most humane methods. For other relevant information of interest to consumers, the nature of this would best be achieved through consultation with key stakeholders.

19. Consultation

Do you support the establishment of a formal consultative forum in Australia, similar to the UK model? If not, why?

Response: There appears to be merit to establish a formal consultative forum in Australia, similar to the UK model.

20. Packaging – no comment

21. Efficacy

Which of the three options presented for retaining (for specific products), reducing or removing efficacy from the current agvet chemicals regulatory system do you prefer and why?

a) Do you support applying option 1 to all crop protection products and non-scheduled veterinary medicines? If not, why?

b) Do you support applying option 2 to scheduled veterinary medicines? If not, why?

c) Are there unmanageable risks or costs if the efficacy criterion was removed or reduced from the regulatory system? If so, could you provide details?

Response: The RSPCA strongly supports Option 3, due to the significant risks to animal welfare (and human safety) relating to the potential future registration of products which have not been assessed for efficacy by the regulator. Consumer and community expectations are that the regulator would be assessing efficacy as well as safety and welfare risks of products submitted for registration. There are potential merits in applicants using independent, qualified external assessors to improve the efficiency of the efficacy review process. There may also be benefits to allow for the need for the same rigour of efficacy for products deemed low risk. However, it is still important to ensure that there is sufficient monitoring of the safety and effectiveness of such products.

22. Use of standards

Would the ability to make greater use of standards be beneficial for applicants? If not, why?

Response: There is some merit for increasing the use of standards to improve efficiency of the registration process but this may need to be limited to low risk products. Also, it is essential that standards are not driven by the industry due to a conflict of interest, but that the regulator has full control.

23. Comparable regulators

Should the regulator utilise prior assessment decisions from comparable regulators to fast track registration where appropriate? If not, why?

Response: There are concerns regarding utilising assessment decisions from comparable regulators but rather than automatic approval being given, there needs to be some caution for products which may pose welfare and other identified risks. For these products, it would be reasonable for the information pertaining to efficacy, safety and environmental risks from comparable regulators to be considered as part of the overall registration assessment. However, animal welfare should be assessed as a separate aspect. For example, many years ago porcine somatropin hormone was developed to improve feed conversion efficiency in pigs and was registered in the USA. However, the administration of this drug required regular injections, which posed welfare risks in relation to handling and restraint as well as the pain of the injection. On this basis, the product should not have been registered for use in Australia. It is understood that this product is no longer registered.

It should be noted that there are also benefits in utilizing existing information from comparable regulators, especially if animal testing can be avoided on the basis that robust information exists.

24. Assessing permits

Is enough being done to address minor use permit applications, if not what more could be done?

Response: It is understood that the process to obtain a minor use permit can be onerous. The RSPCA would encourage the process to be streamlined as much as possible where a product can improve animal welfare outcomes.

25. Chemical reviews

Are there changes that need to be made to the chemical review process to accelerate timeframes for completion? If so, what would these changes be?

Response: Chemical reviews should be conducted in a robust, efficient and timely manner. This is particularly relevant for chemicals which pose risks in terms of development of resistance and also for chemicals which pose high welfare risks and where more humane alternatives are developed. Options to achieve this should be fully investigated.

26. Smart labelling – no comment

27. International network – no comment

28. National regulator working group

Do you support the reinvigoration of the Registration Liaison Committee to focus on its original intent? If not, why?

a) Do you support the proposed new formal consultative forum (chapter 5) in Australia including work on regulatory operations and technical working committees?

Response: There appears to be benefits to having a Registration Liaison Committee.

29. Private sector assessment

Do you support a third-party accredited assessor scheme? If not, why?

Response: This approach has merit particularly regarding the humaneness assessment of chemicals for vertebrate pest control, given that such a system currently operates through the NSW Department of Primary Industry. It may be possible for applicants could access this service on a user pays basis with the information being included for registration.

30. Future technologies

What additional capabilities may be needed by agvet chemical regulators to assess new technology?

Response: In terms of analgesic and anaesthetic product application, new administration methods are being developed for production animals. It is essential that the regulator assess the impacts of new administration methods of these types of chemicals on intended and unintended animal welfare consequences, both positive

and negative. This is especially relevant where new equipment and/or applicators are being used for existing chemicals, e.g. Numnuts for ring castration of lambs; the device for allowing administration of liquid nitrogen to the breech of lambs (mulesing alternative). Animal welfare is not currently included as a criteria for product registration but should be considered as an additional pillar alongside quality, efficacy, safety, environmental risk and trade).

31. Cost recovery – no comment

32. Public good – no comment

Additional comment:

The RSPCA advocates that consideration be given to mandatory reporting of the use of veterinary medicines for livestock production, particularly for products which can impact on the development of antimicrobial resistance, which is becoming an issue of increasing importance for both animal and human health.

References

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