Review of the Agvet Chemicals Regulatory Framework – Draft Report

RSPCA Australia Submission

24 February 2021

1. Introduction

The RSPCA welcomes the opportunity to provide comment on the Draft Report of the Independent Review of the Agvet Chemicals Regulatory Framework (Draft Report) as part of the public consultation process.

The Draft report relies heavily on citing submissions. However, quoting opinions or view from different stakeholders lacks scientific rigour. It is therefore suggested that valid and relevant references contained in submissions should be cited rather than just the submission.

The Draft report contains little information regarding the implementation of recommendations. Key stakeholder engagement, perhaps through the forums and other mechanisms is essential to ensure that the development of implementation strategies is guided by those most effected by any changes.

Another issue which we did not raise in our original submission to the committee but has since come to our attention, is the importance of the Agvet Chemical Framework to recognise the need for registration requirements to reduce reliance on animal testing. This is a significant animal welfare issue directly related to the registration of agvet chemicals. The RSPCA has been liaising with the federal Department of Health regarding a scoping project which has been allocated commonwealth funding. The project aims to investigate the potential for non-animal alternatives to be used for product registration to meet human health and safety requirements. The types of compounds to be included in the scoping project has yet to be determined. There has been significant advances achieved internationally in this area but very little has been done in terms of registration processes for toxicity assessment in Australia. This issue relates to an animal welfare and ethical concerns regarding registration process requirements and is therefore consistent with the fundamental principles in the Draft Report relating to protection of health and welfare of animals.

The RSPCA generally supports all recommendations in the Draft Report which impact on animal health, safety and welfare, with the exception of the following, where specific comments are made.

2. Humaneness of vertebrate pest control chemicals (Recommendation 44)

The RSPCA is very pleased that inclusion of relative humaneness on product labels for pest animal control chemicals has been recommended. The RSPCA believes this will be a significant step in achieving improved welfare of animals affected by vertebrate pest control programs. In general terms, baiting is the least humane method compared to other methods and so overall the inclusion of relative humaneness on product labels will highlight the importance of animal welfare when selecting a particular control method. This should improve welfare outcomes for both target and non-target species. The other benefit will be that greater attention will be focused on more humane methods being developed, including non-lethal humane methods.

(Note: this recommendation has been placed first as it is a top priority for improving the welfare outcomes for animals involved in pest control programs)

3. Effectiveness of Agvet Chemicals (Executive Summary)

In the Executive Summary (on page xiii),

- *Increased protection for the **health and safety** of people, plants, animals, and the environment*

it mentions Increased protection for the health and safety of people, plants, animals and the environment but there is a strong emphasis on surveillance and monitoring.

The RSPCA believes it is essential that there is a commitment to and processes to ensure effectiveness of products rather than relying on surveillance and monitoring to detect efficacy failures. It is not possible to ensure health and safety without assessment of effectiveness being an integral part of the registration process. If a product does not fulfil registered claims, this may pose significant health and welfare risks, i.e., if an analgesic does not produce the desired pain relief or if an antibiotic does not achieve adequate antimicrobial activity. The Australian public would expect product effectiveness to be included as a critical responsibility of government for product registration. Effectiveness should be included as a principle in the Agvet Chemical Framework Report, so that it is clear that this is an integral part of product registration.

4. Anti-microbial resistance

Anti-microbial resistance is a critical issue in terms of being a significant risk to sustainability of livestock production as well as safeguarding animal health and welfare. In many instances anti-microbials are used to help counter flaws in husbandry and management practices, particularly in relation to intensive production systems, where animals are maintained in crowded, sterile environments lacking mental stimulation and where animals are subjected to stressful challenges such as early age weaning. Anti-microbial resistance is a huge problem in terms of which needs urgent attention.

5. Commissioner for Pesticides and Veterinary Medicines Stewardship (Recommendation 7)

Although establishing a commissioner will raise the profile and importance of the regulation of agvet chemicals, the RSPCA has concerns regarding the power and accountability of the commissioner in terms of ensuring that all stakeholder views are considered equally particularly where concerns regarding environmental, human and animal wellbeing are expressed. The commissioner must not be permitted to make decisions without sufficient input from all stakeholders and not be overly influenced by industry and economic considerations.

6. Performance measures (Recommendation 12)

The Draft Report recommends that the Commissioner be responsible for producing a biennial report which will be publicly available. However, it is unclear as to who the Commissioner would report to, i.e. the relevant Federal Ministers etc? It is also unclear as to what the response should be in terms of addressing lack of progress on reforms.

7. Residue monitoring and adverse experience reports (Recommendation 36)

Suggest adding in the last sentence, the word 'appropriate' before ….response action is being taken.

8. Industry quality assurance schemes (Recommendation 49)

The RSPCA has concerns about using industry quality assurance schemes, as the principles abided by government and those by industry are not always consistent. The role of regulation must remain with the government and not those who has a primary incentive which is driven by profit. If this approach is adopted, validated third party accreditation of industry must be the minimum requirement to ensure the system is robust and transparent.

9. Compounded veterinary medicines (Recommendations 68, 69, 70)

It is essential that compounded veterinary medicines are included in the registration process as for other veterinary medicines but there needs to be specific engagement with the veterinary profession and relevant pharmaceutical bodies in terms of implementation of these recommendations.

10. International recognition (Recommendation 87)

The RSPCA is concerned regarding utilising assessment decisions from comparable international regulators in that 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.

11. PIC/S accreditation of the APVMA (Recommendations 115, 116, 117)

Although the RSPCA recognises the importance of ensuring high standards in terms of good manufacturing practice there are concerns that PIC/S accreditation will be cost prohibitive, particularly for smaller Australian based companies. Further investigation regarding the regulatory impact of this recommendation should be undertaken before further consideration is given to this issue.

12. Third party assessors (Recommendation 118)

This is a useful adjunct to the assessment process on the basis that the third-party service providers are suitably qualified and experienced.

13. Cost recovery (Recommendations 120-139)

It is essential that an impact regulatory assessment is conducted before cost recovery elements of the new framework are implemented. Although it is acknowledged that industry should bear fair and appropriate costs, it is also essential that this does not jeopardise access by industry and animal owners of essential veterinary medicines on the grounds of animal health and welfare, maintaining sound biosecurity practices, and for exotic disease preparedness.

Ends.