

19 July 2017



Agvet Chemicals Branch
Department of Agriculture and Water Resources
Via email: agvetreform@agriculture.gov.au

**Re: Consultation on the Agricultural and Veterinary Chemicals
Legislation Amendment (Operational Efficiency) Bill 2017**

The National Farmers' Federation (NFF) welcomes the opportunity to make a submission to the consultation on the *Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017*. The NFF is the peak national body representing farmers and, more broadly, agriculture across Australia. Operating under a federated structure, individual farmers join their respective state farm organisation and/or national commodity council. These organisations collectively form the NFF.

Access to state-of-the-art agvet chemicals is crucial to improving the productivity and sustainability of Australian agriculture. This requires the efficient and timely processing of agvet chemical registration applications by the Australian Pesticides and Veterinary Medicines Authority (APVMA). Accordingly, the farming community welcomes this consultation and is of the view that the proposed Bill would help to streamline agricultural chemicals and veterinary medicines (agvet chemicals) regulation in Australia.

While the NFF is largely supportive of the proposed legislative changes, the NFF requests additional information on proposal 8 "Add antimicrobial resistance as a specific safety consideration". This proposal states that the APVMA should assess the potential for human exposure to antimicrobial resistant microorganisms as a specific safety consideration for chemical products and active constituents. Antimicrobial resistance is an issue farmers take very seriously. The NFF recognises the importance of the prudent and responsible use of antimicrobials and understands the importance of considering antimicrobials as part of the registration process.

Nonetheless, the NFF is concerned about the role of the regulator in determining whether products could increase antimicrobial resistance given that this outcome is not a product specific issue. In particular, the NFF has six major concerns:

- 1) The current Bill concentrates only on antimicrobial usage; however, antimicrobial resistance also arises from a number of intrinsic bacterial mechanisms and environmental considerations that are currently overlooked in the Bill;
- 2) The current Bill excludes the scientific consensus that the biggest driver of antimicrobial resistance in humans is human use. The European Medicines Agency Committee for Medicinal Products for Veterinary Use (CVMP) states that "[it] is recognised that the biggest driver of AMR in people is the use of antimicrobials in

human medicine. The CVMP identifies the continued need to use antimicrobials in the interests of animal health and welfare and considers that the risk management measures applied to VMPs in order to address any public health risk should be proportionate and based upon robust scientific evidence”¹;

- 3) The current Bill does not take into account the evidence relating to the role of anthroozoonotic transmission (two-way or bi-directional transfer between humans and animals) of antimicrobial resistance. There is increasing evidence in both livestock and companion animals that human care-takers appear to be a common source of antimicrobial resistance to their pets and the livestock in their care;
- 4) The livestock industries are addressing the issues associated with the use of antimicrobials (the vast majority of which are not used in the treatment of human medical ailments) through the implementation of Antimicrobial Stewardship Programs;
- 5) The vast majority of antibiotics in use in livestock are not considered antibiotics of importance in human medicine. The proposed amendment gives the impression that critically important antibiotics are used routinely in livestock use and that this is the reason why such an amendment must be included in the legislation; and
- 6) Rulings on antibiotic use impact on the producers’ and clinicians’ (within the various livestock industries) legal and ethical responsibilities to treat sick animals. Treatment of sick animals is a basic animal welfare entitlement and this must be considered in all amendments to the legislation.

The most recent APVMA performance statistics² clearly demonstrate the need for change in the agvet chemical regulation space. In addition, due to strict regulations around the registration of chemicals to the Australian market, many manufacturers refrain from registering those chemicals, necessitating Australian farmers to use outdated products. Hence, the NFF is looking forward to working together with the Department of Agriculture and Water Resources to progress the much larger and still outstanding agvet chemical reform. This will include an accelerated approvals process, tailoring effort to risk, and helping the APVMA to be more efficient.

NFF would be grateful for the opportunity to clarify the full implications of proposal 8 of the Bill. For further information on this submission, please feel free to contact me at the office on 02 6269 5666.

MARK HARVEY-SUTTON
Manager Rural Affairs

¹ See European Medicines Agency *CVMP strategy on antimicrobial 2016 – 2020* at www.ema.europa.eu/docs/en_GB/document_library/.../11/WC500196645.pdf

² See APVMA Quarterly report: January – March 2017 at <https://apvma.gov.au/node/26841>