CANADIAN MEAT COUNCIL
CONSEIL DES VIANDES DU CANADA

FEEDBACK FORM

Consultation on Proposed Changes to the *Food & Drug Regulations* for Antimicrobial Resistance related to Veterinary Drugs

Submit Comments to:
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Date: September 15, 2016

Comment *(Please note if the comment relates to the regulatory proposal or the explanatory note)*	**Suggested Revision**
Canada Gazette Part 1 July 2, 2016 Page 2366 *Ensuring the quality of APIs for veterinary use*	Although the proposed changes substantially strengthen the requirements for veterinary use of APIs, we believe that the use of APIs should not be supported in food animals. In other words, we should not use an "uncontrolled" API alone if it is not "stabilized" in a compound (buffered powder, pill, liquid, etc.) and commercialized by a pharmaceutical company. The use of APIs is motivated by cost savings or lack of availability of suitable veterinary drug products. In principle, cost savings should not preclude the use of a registered veterinary drug with proper dosage and quality control. While we recognize the requirement for Establishment Licenses will enhance

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	control and competency of compounding activities, we request that compounded products not be permitted in food animals in order to minimize risk of residues and improper potency and dosing.
Canada Gazette Part 1 July 2, 2016 Page 2367 *Controlling the own use importation of veterinary drugs*	After reviewing the proposed changes and explanatory note, it remains unclear which kinds of drugs will be in List B, and what veterinary oversight requirements will be in place to ensure proper use of those drugs. While we recognize the provision of this list will enhance access to drugs of necessity, particularly for minor species, we request that clearly defined veterinary oversight requirements remain a priority for the use of veterinary drugs in food animals.
Canada Gazette Part 1 July 2, 2016 Page 2368 *Gathering information that supports AMR surveillance*	While reporting of veterinary drug sales will improve Canada's overall understanding of veterinary drug use, it is only a crude metric. In order to accurately relate veterinary drug use to antimicrobial resistance risk, usage needs to be reported in population-corrected units. This information is worthwhile but complicated to compile, therefore modern electronic data collection systems that collect blind data in real-time are crucial to support compliance by producers and veterinarians. The veterinary, agricultural, and human health industries must all be held accountable to the same level of transparency to ensure all parties are adopting the same ethical standards for antimicrobial use.
Canada Gazette Part 1 July 2, 2016 Page 2374 *Cost-benefit statement – Costs*	This list includes 'livestock and poultry mortality' as a potential impact of limiting access to antimicrobials. Ensuring the welfare of our livestock and poultry is extremely important to organizations, producers, and consumers. The non-quantifiable impact of potentially compromising animal welfare should be included in addition to the potential impact to mortality rates.

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Canada Gazette Part 1 July 2, 2016 Page 2379 *Own use importation and price differential*	In the list of products commonly accessed through OUI, vaccines such as autogenous killed *Salmonella* and *Adenovirus* products are included. It is our understanding that vaccines are not veterinary drugs but rather are biologics and therefore subject to oversight of veterinary biologics under the *Health of Animals Act and Regulations*. Access to vaccines is critical for minimizing antimicrobial use in food animals and so we assume no limitations on vaccine accessibility will be imposed as a result of the proposed changes to the *Food & Drug Regulations.*
Canada Gazette Part 1 July 2, 2016 Pages 2386 to 2387 *Small business lens*	While we recognize that many livestock and poultry farms fall under the scope of small businesses, it is important they still be treated as commercial enterprises with an accountability to supply high quality, safe products to their customers. Certain aspects of food animal production, for example on-farm feed milling for own use, are not subjected to the same regulatory oversight as commercial enterprises. It is a priority that those risks and loopholes be identified and closed during this and related regulatory amendment processes.
Canada Gazette Part 1 July 2, 2016 Pages 2386 to 2387 *Ensuring the quality of APIs for veterinary use*	It is critical that quality in the compounding of APIs be assured in the amended regulations in order to prevent development of antimicrobial resistance, prevent the occurrence of violative residues, and maintain consumer trust. We support the adoption of 'the Initial Option' as a long-term means to ensure APIs are being used properly by all parties, including veterinarians.