



**Canadian Association of Poultry Veterinarians/L'Association Canadienne des
Vétérinaires Aviaires**

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Veterinary Drugs Directorate,
Health Products and Food Branch
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Subject: Consultation on Appendix E-2 Viable Microbial Products (VMPs)

Dear Regulatory Officer,

The Canadian Association of Poultry Veterinarians (CAPV –ACVA) appreciates the opportunity to comment on Appendix E-2: Viable Microbial Products (VMPs). Access to viable microbial products and communication of their use is critical to the success of the CAPV-ACVA membership and the Canadian poultry industry that they serve as the key challenges of Food Safety, Antimicrobial Resistance/Use and Bird Welfare each have microbiota as the fundamental issue.

Accordingly , the CAPV-ACVA is pleased that the Veterinary Drugs Directorate (VDD) of Health Canada and the Feed Division of the Canadian Food Inspection Agency (CFIA) have created this document to facilitate registration and understanding of VMPs by increasing the flexibility for classification of potential products i.e. “The classification criteria for VMPs have been reconsidered, recognizing that the mode of action of these products may involve modification to the gut microflora and the gut environment without necessarily classifying them as veterinary drugs”. Similarly, “VMPs classified as feeds may fall under a new category: “Gut modifier (gastro-intestinal modifier)” which may be indicated on the label” is also welcome although this claim is not listed in Table E-2.1.

The CAPV-ACVA appreciates that these changes took about 8 years of advocacy, and their position is that regulators, on an on-going basis need to be enablers of products coming to the Canadian market. As stated by the Advisory Council on Economic Growth, 2017, ”*Regulation has to be agile and adaptive enough to address the ways that innovative companies will continuously rewrite the rules of competition ensuring sufficient oversight to protect the public interest without posing obstacles to innovation*”.

Section 3.1 Properties of Microbial Strains raises questions as to what is/will be the criteria for review of an application e.g. “Strains with known antimicrobial properties such as : bacteriocin production,

antimicrobial peptide production and/or bacteriophages , may be considered drugs”. A wide range of Gram (-) and Gram (+) bacteria have bacteriocin activity and all bacteria, as they evolve to survive will develop defense mechanisms. Depending on criteria, will any products come to the Canadian market as VMPs?

“Products under the Gut modifier category would also carry a nutritional or production /performance claim consistent with products regulated under the Feeds Act and Regulations and examples of which can be found in Table E-2.1.” This requirement will be welcomed by sponsors that presently have products on the market with production claims i.e. there is opportunity for additional claims for an existing product. Conversely, an applicant with a product that meets criteria for VMPs may not have performance data for registration and such products will not come on to the Canadian market.

“Probiotics” and “Competitive Exclusion” terminology is excluded in Appendix E-2: Viable microbial products (VMPs)? Probiotics can be defined as “Live microorganisms which when consumed in adequate amounts, confer a health benefit to the host”. Undoubtedly , the terminology “Viable Microbial Products “was favoured over “Probiotics” for Appendix E-2. The fact remains that the term “Probiotics” is permissible by Health Canada when specific criteria are satisfied for use in food and natural health products. Consumers, whether they buy food or own animals, understand “Probiotics”. It will take some time for animal owners to understand “Viable Microbial Products” as opposed to “Probiotics” in communications. It is to be appreciated that all “Probiotics “are “VMPs” but not all “VMPs” are “Probiotics”.

“Competitive Exclusion” is a term that has been used to describe the protective effect of the natural or native bacterial flora of the intestine in limiting the colonization of some bacterial pathogens. Access to products that exert the “Competitive Exclusion Principle” will benefit Canadians in at least two important ways: Salmonellae control and Reduction of Antimicrobial Resistance. As for Salmonellae control, chicks and poults are hatched (born) like all newborns –with no gastro-intestinal flora. Seeding the gastrointestinal tract with favourable flora from the mother presents a healthy scenario. In today’s poultry production, this would be accomplished by spraying newly hatched chicks and poults with gel droplets containing a VMP that contains organisms that colonizes the gut before Salmonellae can. Competitive exclusion would be a most useful tool in combatting antimicrobial resistance by using VMPs (preferably via water) upon cessation of antibiotic treatment. Antibiotics inhibit/kill susceptible flora, leaving antibiotic-resistant organisms. Use of a VMP post- treatment would fill the void left by the treatment and give competition to antibiotic –resistant organisms.

Table E-2.1 lists general health claims for Veterinary Health Products that are well received by members of the CAPV-ACVA but Table E-2.2 lists Forcible Administration (e.g. bolus, tablet, drench) as only mode of oral administration. Forcible Administration is not an option in commercial poultry production. Accordingly, CAPV-ACVA respectively requests that water and gel be approved in Table E-2.2 for Veterinary Health Products. Note: coccidial vaccines are routinely administered by spray or gel to newly hatched chicks or poults with gel administration preferred because the droplet size is constant, droplets adhere to the fluff, and birds can easily preen the droplets, resulting in a full dose of vaccine being delivered to the target (which is the gut).

The CAPV-ACVA applauds efforts that have led to the release of Appendix E-2: Viable Microbial Products but sense that it is not a final document (i.e. not cast in stone) but one that is adaptable to change and inputs, depending on experience, new developments and needs. Accordingly, as an aid to decision-making going forward, the CAPV-ACVA presents the following synopsis of needs and challenges of poultry veterinarians and the Canadian poultry industry that they serve:

1. Food Safety

- (i) Salmonellae –Salmonellae infection in humans remains a serious threat despite extensive programs (Appendix A) to reduce transmission from animals. Salmonella was isolated from forty-six percent (46%) samples tested in 2016 with approximately 10% of isolates resistant to Category I and II antimicrobials. CIPARS FARM SURVEILLANCE POULTRY (broilers, turkeys, layers) 2016 Annual Report Overview.
- (ii) Campylobacter remains a major cause of foodborne diarrheal illness in humans. Campylobacter was isolated from seventeen percent (17%) of samples from chickens tested by CIPARS in 2016, and of these, approximately fifteen percent (15%) were resistant to ciprofloxacin.

2. Antimicrobial Resistance and Use

Antimicrobial resistance is a global crisis that is being addressed by Health Canada in policy and regulatory changes coming from “Antimicrobial Resistance and Use in Canada: A Federal Framework for Action”. Pillars include surveillance, stewardship and innovation. In response to consumer and market demand, Chicken Farmers of Canada and Turkey Farmers of Canada have embarked on antimicrobial use reduction strategies to eliminate the preventative use of Category I, II and III antibiotics. Note: Voluntary elimination of the preventive use of Category I in commercial chickens and turkeys in May 2014, and genetic stock in May 2015. Elimination of preventive use of Category II by end of 2018 (chickens and turkeys) and Category III by end of 2019(turkeys) and 2020(chickens). Outcomes of these antimicrobial use reduction strategies are yet to be determined but increase in disease of the intestine, e.g. necrotic enteritis may be an issue, and possibly increased incidence of Salmonellae?

3. Bird Welfare

For 50 + years, antibiotics have been used for the prevention of disease in poultry. Disease in poultry is a welfare issue, so veterinarians must be prepared to work closely with their clients to treat birds when necessary. The American Association of Avian Pathologists (AAAP) position on Antimicrobial Use and Bird Welfare (Appendix B) serves as a guide to appropriate treatment with antibiotics .Based on the experience of poultry production in the E.U. and the USA, alternatives such as herbals, essential oils, organic acids, enzymes, medium chain fatty acids, and viable microbial products can contribute as “gut modifiers” so birds do not become sick and have to be treated.

Conclusions

- 1. Appendix E-2: Viable microbial products (VMPs) are timely in view of initiatives to reduce antimicrobial use of products approved to prevent bacterial disease of the gut.
- 2. Viable microbial products will not and are not intended to replace antibiotics.

3. Viable microbial products (VMPs) can serve as “Gut Modifiers”; promote a healthy gut flora and maintain the balance of healthy flora.
4. Appendix E-2: Viable microbial products provide opportunity to sponsors to register their products in Canada and to educate their clients in the role of VMPs.
5. Registering VMPs as drugs (via VDD) remains an option but an expensive one with the demand on resources for research, maintaining Drug Manufacturing Standards, and Registration/Renewal Fees.
6. The Canadian Veterinary Biologics Establishment currently licences VMPs (Vaccines) against Salmonella, E. coli and coccidiosis. Why can this Institute not register VMPs with appropriate claim(s)?
7. Claims for veterinary health products are in line with the needs of the Canadian poultry industry but need to be able to be administered via water and gel spray (preferred).
8. Viable microbial products (VMPs) can be much needed useful tools to complement existing Government Programs to control Salmonellae and Campylobacter.
9. Competitive Exclusion Principle Exists and is Real! Two species competing for the same limiting resource cannot coexist at constant population values. CE can positively influence Salmonellae and antimicrobial resistance outcomes.
10. Viable microbial products (VMPs) when used strategically in a complete health management program implemented under the supervision of veterinarians in cooperation with animal nutritionists can favourably influence the outcome of Food Safety, Antimicrobial Resistance/Use and Bird Welfare.

Respectfully submitted,

On behalf of the members of The Canadian Association of Poultry Veterinarians/L'Association
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Appendix A:

Existing Programs to Control Salmonellae

1. Fluff sampling in all registered hatcheries every 6 weeks-will identify all Salmonellae.
2. Environmental swabbing/testing in all federally registered egg grading and breaking stations-will identify all Salmonellae.
3. Carcass wash in federally registered establishments exporting to the USA-follows the APHIS testing and standards; will identify Salmonellae only to the genus level; no serotyping. Campy?
4. Domestic and Imported Ready to Eat Meat-tests for Salmonella, Staphylococcus, E.coli and Listeria.
5. Imported shelled and liquid eggs
6. Additional testing requirements for companies that export especially to the EU.

Appendix B:

The American Association of Poultry Pathologists (AAP) Position on Poultry Welfare and Careful Use of Antibiotics (attached)