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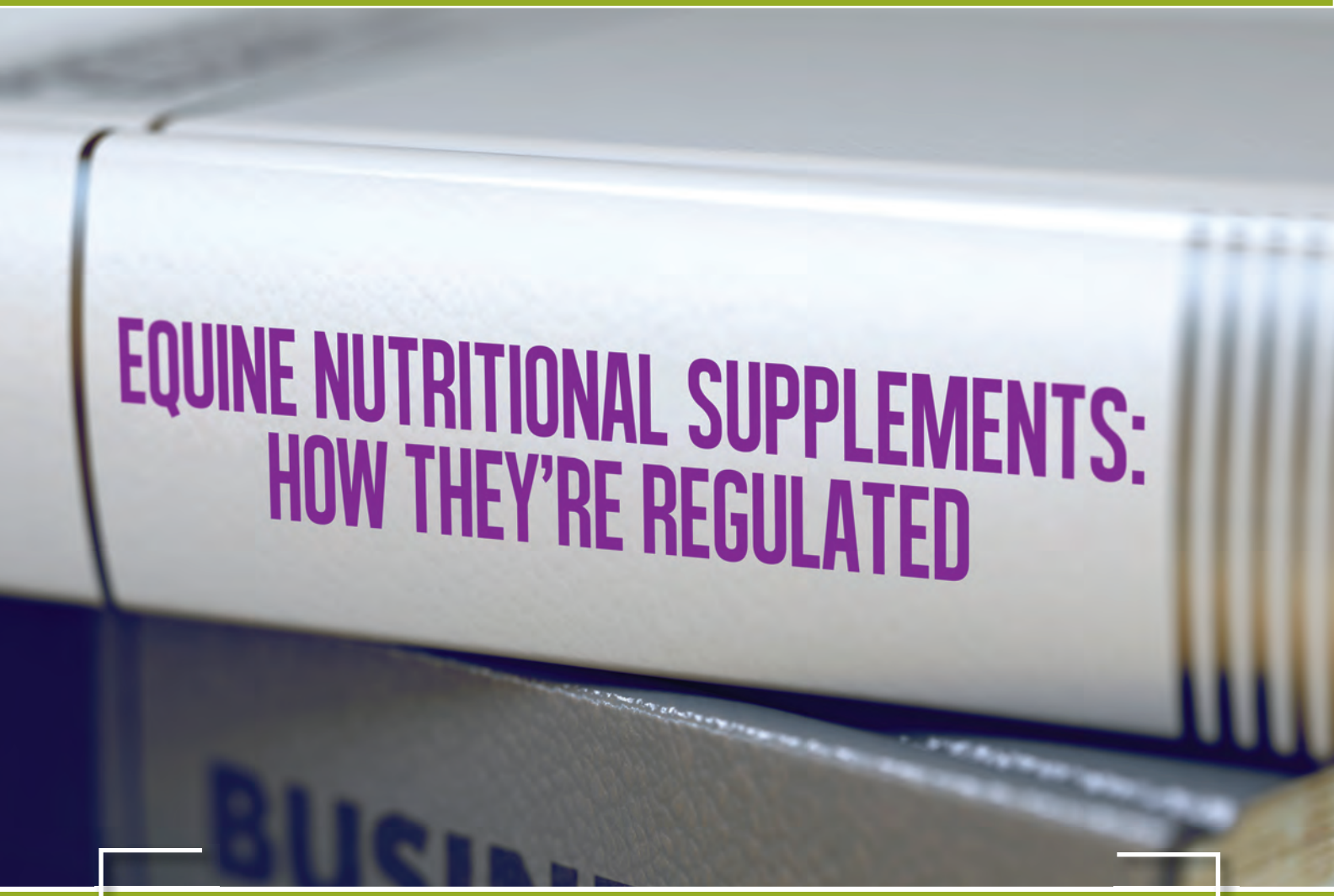

EQUINE NUTRITIONAL SUPPLEMENTS: HOW THEY'RE REGULATED

The nutritional supplements market has exploded over the last couple of decades. While these supplements bring many benefits to our horses, we also need to ensure we can trust the products we're using. If a company makes a claim, for instance, is it supported by clinical research? This article explores the regulatory process in the U.S. and Canada, and what horse caretakers need to know.

REGULATING EQUINE DIETARY SUPPLEMENTS IN THE U.S. AND CANADA

By Cindy MacDonald

In the United States, supplements for animals are considered either a food or a drug, depending on the intended use. They have no category of their own. The Food and Drug Administration (FDA), Center for Veterinary Medicine (CVM) regulates both categories through the Federal Food, Drug and Cosmetic Act (the Act).

The Act does not require that animal foods have pre-market approval by FDA-CVM, however the ingredients must be approved for use in animal food/feed. It does require that animal foods, like human foods, be pure and wholesome, contain no harmful or deleterious substances, and be truthfully labeled.

As the human supplements market expanded in the last couple of decades, so too did interest in the supplements market for companion animals. As more and more brands hit the shelves, it became difficult to monitor which products met the requirements. The industry struggled through several failed committees as well as threats to remove categories of products from shelves in certain States. Finally, in 2001, the National

Animal Supplement Council (NASC) was founded to help oversee to the erratic regulatory environment.

TRANSPARENCY IS KEY TO REGULATION

The non-profit organization represents approximately 95% of brands in the U.S., and their members and affiliates include manufacturers, marketers, raw materials suppliers, distributors, regulators, veterinarians, retailers, pet professionals and animal owners.

The NASC aims to protect companion animals, namely dogs, cats and horses, from potentially harmful nutrition or health supplements through a transparent process. They work with federal and state regulators to ensure standards for these products are high quality, reasonable, responsible and consistent.

Prospective NASC members who sell branded products are required to sign a written NASC Code of Conduct Agreement, pledging the company will follow faithfully the requirements of membership.

If NASC supplier members meet specific criteria of ongoing adherence to the organization's policies and standards – verified by an on-site quality audit – they are granted permission to use the NASC Quality Seal on their product labels, websites, product literature and advertising.

This voluntary approach for companies is working well due to the cooperation embraced by industry participants, regulatory agencies and downstream purchasers such as veterinarians, retailers and animal owners.

In addition, NASC implements an Adverse Event Reporting System to handle complaints involving an animal health or nutritional supplement that's allegedly had a negative physical effect or created a health problem. The member must investigate and resolve each adverse event, and report monthly to NASC, whether there's been an adverse event or not. Their system tracks these adverse events by ingredient or product, as well as product sales by SKU. Even though the information is confidential for all NASC members, the system and information are available to the FDA.

www.animalsupplements.org

REGULATORY OVERSIGHT IN CANADA

By Wendy Pearson

The Equine Supplements Space represents big business for manufacturers and retailers. Compared with products available even as recently as a decade ago, horse owners can find "self-help" supplements for virtually any and every equine ailment. While there can be much to be gained from providing high quality, efficacious feed additives to horse diets, there is a general misunderstanding amongst horse owners about this very colorful product category. After all, as horse owners we are accustomed to regulatory oversight for our feed companies and our pharmaceutical companies, and it naturally follows that such oversight must be protecting us when we buy supplements too. Right? Well, this is unfortunately not a simple yes or no answer. Here's a brief summary of the regulatory environment surrounding equine supplements, and what changes are afoot!

Canadian equine supplements are regulated through Health Canada but, until very recently, the task had been downloaded to a private company who administered an interim notification program called 'The Low Risk Veterinary Health Products Program' (LRVHP; *lrvhp.ca*). This program was a voluntary notification program, which allowed equine supplement manufacturers to apply for blessing from Health Canada on their low-risk health product. At its inception, the LRVHP was a big victory for horse owners, as it meant that, for the first time in Canadian history, horse owners could enjoy a new level of confidence that the product was actually safe for horses.

The LRVHP program was a great first step at protecting the safety of our horses, however, problems arose because the program was voluntary and many supplements were not even captured by the program. Only products containing ingredients specified on the "admissible substances" list were eligible for notification through this program. That meant many herbal products containing herbs that did not have *documented* history of use *in horses* would not be eligible. There was an opportunity for manufacturers to apply to have a new ingredient added to the admissible substances list, but unless they could provide historical evidence of use and safety in horses it was pretty unlikely that the substance would be added.

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DID LRVHP PROTECT CONSUMERS FROM PRODUCTS THAT DON'T WORK?

Safety was King when it came to LRVHP, but the program didn't solve all our problems with equine supplements. It still left the responsibility of providing efficacious products in the hands of the manufacturer. And while many companies claimed to manufacture products "based on science", this science was almost always extracted from literature in the public domain and NOT from research on their individual blended product. This was a big problem, since dangerous interactions could occur. Companies needed to support their products with research that was *specific to their product*, and *specific to horses*. The trouble was – and continues to be – that research on horses is expensive and many companies manufacturing equine products are small- to mid-sized companies without much of a budget for research. The government does provide some financial help in this respect, but unfortunately many companies aren't aware of these programs. And most don't do this type of research.

The LRVHP program was a great help, but….

Even with the LRVHP, it remained up to the consumer to demand efficacy research from their favorite supplement manufacturers. Also, quality assurance standards such as GMP (Good Manufacturing Practice) and HACCP (Hazard Analysis Critical Control Points) were not mandated by the program, leaving consumers at risk for contaminated or adulterated products.

So, a next step beyond LRVHP was needed.

THE NEW REGULATORY ENVIRONMENT IN CANADA

On November 13, 2017 Health Canada implemented amendments to the Food and Drug Regulations to include a new category of products named 'Veterinary Health Products' (VHPs).

Hordeum vulgare

Fritillaria thunbergii

These amendments take the equine supplement industry a step forward towards an improved regulatory environment, and safer, better products for horse owners. The program provides a few key improvements over the previous LRVHP program. First (and perhaps most importantly) the program is no longer voluntary, and *any* company manufacturing, importing, distributing or selling equine supplements is obligated to enlist in this program. Second, all products must be manufactured under a minimum quality assurance standard of GMP. The list of allowed ingredients within VHPs is provided as List C: Veterinary Health Products (*canada.ca/en/public-health/services/antibiotic-antimicrobial-resistance/animals/veterinary-health-products/list-c.html*) and contains a vastly expanded list compared with the previous Admissible Substances List of the LRVHP. And lastly, companies participating in this program are obliged to report any serious adverse reactions to their products to Health Canada.

So, with the key changes seen in this new program, horse owners can look forward to improved standards for equine supplements in the coming months. However, remember that despite the improved regulatory environment provided by the VHP program, it still does not require suppliers of equine supplements to do any efficacy research on their products. This level of due diligence still lies at the feet of responsible manufacturers, and is only likely to be observed if consumers like you demand it!

Wendy Pearson completed an MSc (Nutritional Toxicology) and a PhD program (Biomedical Toxicology) at the University of Guelph with specialization in medicinal herbs and nutraceuticals for horses. She has accumulated over 20 peer-reviewed research papers, abstracts and book chapters on veterinary natural supplements. Wendy spent two years as a scientist at a multinational research and development consulting firm, with a specialization in natural veterinary drug development, followed by a post-doctoral research fellowship at the University of Guelph in clinical nutrition for livestock. Since 2016, Wendy has been employed as Assistant Professor of Equine Physiology in the Department of Animal Biosciences, University of Guelph.