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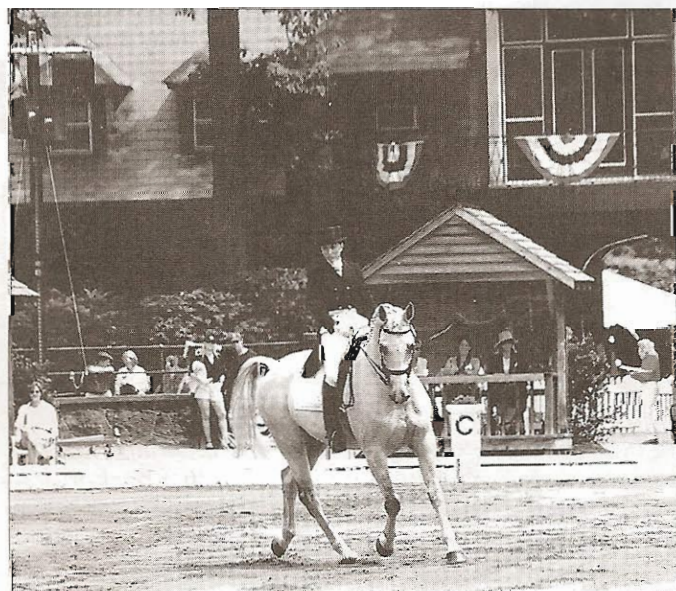
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Managing Risk In Supplements

The president of the NASC works to help ensure you're getting what you're paying for in a supplement.

With tenacity and compassion Bill Bookout has risen from foot soldier to general in the ongoing struggle for accountability in the animal supplements industry. As a founding member of the National Animal Supplement Council (NASC) and president of the nonprofit organization since early 2002, Bookout wants consumers to be able to confidently select the safest and most accurately labeled products.

What has evolved for NASC between its founding in 2001 and today?

Accountability was our first goal. In our first three or four years there was a lot of hesitation and doubt (by federal agencies and others) that we could pull this off. Up until 2005, our focus was toward establishing credibility. Since then, we've seen several big steps realized: First, our credibility is significant with U.S. regulatory agencies like FDA (federal Food and Drug Administration), the Center for Veterinary Medicine (CVM), and AAFCO (Association of American Feed Control Officials), and our role in cooperatively working with such groups has increased. Our membership continues to grow, which is also beneficial to these agencies, and finally, NASC has achieved a consistent system of standards and tracking.

The last five years have given NASC a good foundation for formulating long-term solutions for an issue previously ignored or relatively unknown to consumers: that there is no category for dietary supplements for animals. Congress remained silent on mentioning animals when they passed legislation for human products in 1994. So we are engaging groups to establish policies, meet objectives, and demonstrate the benefits of responsible action.

Since Horse Journal last looked at NASC in 2005, companion animal and

horse owners faced frightening and sometimes tragic consequences of toxic melamine-laced canned cat and dog food, and saw a multi-state precautionary recall of Purina feed in response to possible aflatoxin contamination. What is NASC doing to rebuild consumer confidence?

That's a great question. Initially, at the onset of the melamine incident,

the FDA did not know if the specific source of the problem was wheat gluten.

We went into our NASC Adverse Event Reporting System (NAERS) records, which track over 6,000 products, over 850 individual ingredients, and to date, represent approximately 21 billion bytes of information, and by

Bill Bookout

In addition to his role as NASC president, Bill Bookout is president of Genesis Limited, which he founded in 1999 to provide feed and non-feed products for companion animals. Prior to that, he spent 15 years in the human medical device and animal health industries, including executive positions with Medex Medical, All-Care Animal Referral Center (a specialty referral veterinary hospital) and AnaMed International, and as Director of Sales and Marketing for Marquest Medical Products. Bill received his bachelor's degree in physical sciences from the University of Wyoming and an MBA from Pepperdine University.

To fully appreciate his role also requires a brief overview of what NASC does and why: Founded in 2001, NASC is an all-industry association of stakeholders whose goal is to promote the health and well-being of non-human food chain animals (i.e. horses, dogs, cats) that are given supplements by their owners, and to protect and enhance the integrity of the animal-health-product industry. The cornerstone of that mission is to work with government officials to create a legislative and regulatory environment that provides fair, reasonable, responsible and nationally consistent information and standards. NASC member companies are required to undergo rigorous independent audits of their facilities. Upon successful completion of an audit, somewhat like the "Good Housekeeping Seal of Approval" we grew up seeing in our mothers' pantries, members may then display a NASC Seal of Quality, assuring consumers they are committed to the "highest current standards of quality in the industry today." Simply put, before NASC, the 'snake oil salesmen' of a bygone horse-and-buggy era were still alive and well: there was no regulatory body overseeing animal supplements for consistency of ingredients, truth in labeling, or safety.



NASC's Other Voices

NASC has come to fruition through the hard work of supporters on the regulatory and production sides of the coin, including Susan Domizi, founder of SOURCE, Inc., and Paal Gisholt, president and CEO of SmartPak Equine and the member of the NASC Board of Directors responsible for the NASC Adverse Event Reporting System (NAERS).

SOURCE, Inc. was one of the first companies to join NASC and face its audit system. "The NASC is the best thing to happen to the equine nutrition industry since I became involved over 35 years ago," said Domizi. "Way back then, it was like a Wild West show. 'Snake oil' products were common and 'caveat emptor' (buyer beware) was good advice. We (SOURCE, Inc.) were passionate about product quality, safety, customer satisfaction and service and thought we were doing a great job, but it took NASC to show us that we had a problem.

"Our quality controls were in our hearts and heads, not spelled out on paper. If we had hopes of passing an independent audit so that we could display the NASC Seal, every step we took to ensure product quality and safety would have to be spelled out in writing. Then the audit (which took five days) had us verify we actually did everything we claimed. We were proud to receive a Compliance Rating of A on the first audit and again on the second. We are a much stronger company now. I sleep better at night knowing that we have documented Standard Operating Procedures (SOPs) that can be relied upon to ensure product quality. It is exciting to see more companies implementing the necessary procedures so they too can earn the right to display the NASC Seal. This translates to a steadily increasing number of safe, quality products that consumers can rely on."

Consumers can also rely on the fact that if their horse or companion animal suffers an adverse reaction, or any negative incident occurs around a product, NASC will not only listen but can respond with the rapidity afforded by modern technology and database management. Paal Gisholt's work with the NASC Adverse Event Reporting System (NAERS), including playing a role in its design (modeling it on a similar incident system originally used by SmartPak), assures precisely that. "NAERS is an incredible database of product usage that surpasses anything even in human supplements. It's a Web-based system requiring monthly log-ins by all NASC members. It's a sophisticated, relational database that can link patterns of adverse health reactions to products or ingredients and facilitate their investigation. And it happens in 'real time,' each and every month." NASC conducts 'dummy tests' to ensure members comply with reporting any issue, even if the manufacturer doesn't believe the product was at fault. So far, over a billion administrations of supplements have been tracked, and the reporting rate for adverse events averages less than .31 incidents per million administrations of supplements sold.

"As small as this number is, it is even more significant when considering the broad definition of an Adverse Event: a complaint for a product linked to any negative physical effect or health problem that may be connected to, or associated with, use of the product.

Even transient events like vomiting, diarrhea, lethargy, etc. would be reported, recorded and evaluated. Reporting an Adverse Event also does not mean that it was necessarily associated with the use of a product, however we cast a broad net because FDA-CVM asks us to."

Echoing the sentiments of NASC's president, Gisholt says, "We will do the things we can to help ensure the safe use of these products. There is no absolute assurance of anything in life, but we can commit to working hard to provide an early warning system."

utilizing that system, were able to track all products with grain-based protein sources and issue summary reports to the regulatory agencies.

Once wheat gluten was specifically identified, within 24 hours NASC had reports issued to state agencies and members denoting products containing wheat gluten so those sources could be confirmed. Fortunately, no NASC members' products were affected by that recall.

Three key factors came out of Senate hearings in 2007 when examining issues surrounding the contamination of pet food: One, it raised questions about general management practices (GMPs) and thus raised quality-control standards; two, it alerted industry and regulatory agencies to the existing problem of having no early warning system in place for incidents like this; and thirdly, there was no verification system to prove when implementation of corrective measures were taking place.

No system of GMPs is perfect, but NASC has a rigorous audit system where every member must provide its ingredients and pass an on-site inspection to verify that all its requirements are met. Consumers can feel confident knowing that it is mandatory to NASC membership that companies input 100% of their ingredients, including type and quantity, into our NAERS database. NAERS also requires members to record the number of doses sold of each product, as well as adverse reports from consumers, and gives FDA direct access to that data.

NAERS Serious Adverse Events are defined as those with a transient incapacitating effect (i.e., rendering the animal unable to function normally for even a short period of time, such as a seizure) or non-transient (i.e., long-term or permanent) and requiring follow-up with a veterinarian.

Have trends toward "green" and/or "natural" products been a boon or a bother?

Interestingly, when the Holistic Veterinary Council met in Nevada, Canada sent a representative to see what we're doing down here in the States. Natural animal care trends suggest the U.S. market spends \$1.3 billion annually and that is projected

GUARANTEED ANALYSIS:

Each Level Scoop (32.4 Grams) Contains:

Glucosamine Sulfate	1230 mg
N-Acetyl Glucosamine	390 mg
Methylsulfonylmethane	390 mg
Yucca Powder	1650 mg
Stabilized Rice Bran	28.716 g

When you look at a guaranteed analysis, how do you know you're truly getting what they claim?

to increase—in the companion animal and horse markets—to \$1.7 billion by 2012. People see these animals as extensions of their family, and as more people look for natural products to maintain quality of life and health, or manage health/age-related components, they are placing a premium on the same products for their animals. I was delighted to see Canada take a different approach and send a rep to an event here to see what we're doing. I hope we can learn something from them about overseeing animal supplements. Health Canada seeks to engage industry experts and develop a system of cross-functional teams from many stakeholders, from those in the industry to consumers to academics. I hope NASC can help set a good example of responsible conduct that others can learn from and we can learn from also. I don't mean to suggest our system is perfect. This is a process of continual improvement. There are deficiencies in every system.

So what are some of those deficiencies facing NASC?

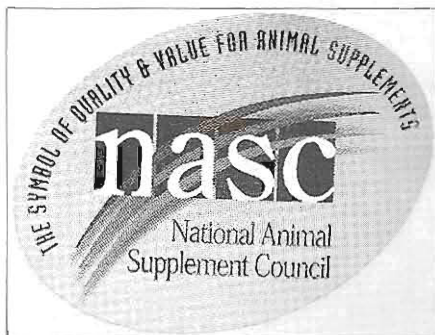
One of the greatest challenges still facing this industry is the need for more evidence-based support. Naysayers demand that animal supplements still need more clinical studies, research, etc. No one asks why there isn't more research and it's because of such limiting factors as U.S. courts saying you cannot patent "natural" ingredients. So there's no incentive for research if it's not going to be protected by a patent so a company can recoup the money it invests into research.

Where we will be seeing significant benefits is through establishing standardized testing and methodologies. For instance, there is still no single validated standard testing method

for chondroitin, which is widely recognized for its benefits as a joint product. As more testing methods are required and implemented, the consumer will get more accurate information.

Two things remain true: Companies that make claims that seem too good to be true probably are,

and cheap products are cheap for a reason. There is no substitute for independent consumer research and review of companies offering products you want to use for your animal. Call and ask a company, who formulated your products? Who can I call for a



Products made by companies who are members of the NASC have this seal.

technical question and how are they qualified and educated to respond to me? Ask questions.

Companies that act irresponsibly cast a shadow on everyone. The NASC Seal on a product's label means that company has been audited. However, there is still no substitute for knowing the company you do business with.

The wheels of government grind slow but fine, and the FDA is cracking down on unsubstantiated claims by animal supplement makers. In September 2008, the FDA issued a warning letter to Drs. Foster and Smith regarding claims for preventing/treating osteoarthritis in dogs (see http://www.fda.gov/foi/warning_letters/s6915c.htm).

NASC is very supportive of regulatory action against irresponsible companies. If you can get the majority of individuals to cooperate with regulatory agencies, supported by downstream consumers and retailers, it can lead to

effective industry change. Consumers help implement change.

If you, the consumer, can implement change by purchasing products from companies that display the NASC Seal, then the NASC can follow through with responsible, fair regulation and enforcement.

That's not to say that animal supplement producers who are not members of NASC are irresponsible. Many are still very responsible, but it's the fly-by-night companies that give us all a bad name. In comparison, those companies that have complied with NASC standards and bear the NASC Seal have demonstrated their desire to act responsibly and do the right thing.

We hope consumers support NASC because of what we're doing, and support the companies who are part of that solution, which at the end of the day will benefit everyone. Much of what NASC does is like riding a dressage test. If we're doing our job right, it's a quiet, smooth performance.

What's on the NASC horizon in 2009?

We're entering our next phase and creating a definitive pathway toward long-term solutions. It's a global marketplace out there, and we're seeking to cooperate with other countries, like Canada, as well as continuing our work with regulatory agencies here.

We'd like to establish and continue to grow our membership and keep our eye on the prize of establishing greater industry consistency. The greater the consistency in the products we can offer consumers, the higher their confidence will be in what we can achieve.

We recognize that there is a paradigm shift in our society, that companion animals and horses have been incorporated into our lives as extended family members. But let's not let the pendulum swing so far in the other direction as to risk litigation. Our society has to be careful to not shift priorities so much that we get into legal complications over animal care. Currently, there is a good balance. Let's keep it that way.

No system can assure that any product is 100% safe, but we can manage risk and put standards into place that keeps uncertainty to a minimum.

Article by Horse Journal staff. [E]