



# The Veterinary Oral Health Council

## Recognizing Efficacious Pet Dental Products

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*The Veterinary Oral Health Council is sponsored by the American Veterinary Dental College (AVDC), the specialist organization for veterinary dentists. The VOHC awards a Seal of Acceptance to pet products that meet established standards in helping to retard plaque and tartar.*

### The Creation of the VOHC

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The idea of professional certification of veterinary dental products emerged in the 1980s. In 1989, an open meeting was held during the Veterinary Dental Forum to discuss the need for and potential issues associated with endorsing dental products. It was recognized that, absent any objective means of recognizing efficacious products, veterinarians and the pet owners could be confused by claims in the plaque and calculus retardation products market.

In 1991, the AVDC sponsored a meeting on veterinary dental product endorsement which included presentations by representatives of AAHA, the American Dental Association, the AVMA and the FDA's Center for Veterinary Medicine. The need for a system was acknowledged, along with concerns about conflict of interest and other ethical issues, financial and liability implications and credibility.

Further discussion continued under the sponsorship of the University of Pennsylvania in 1994 with the naming of a consultant panel. The panel—35 veterinary dentists, dental scientists, representatives of relevant organizations, including the American Dental Association (sponsor of the ADA Council on Dental Therapeutics "Seal of Acceptance" system), AVMA and AAHA—reached consensus on developing a product review and acceptance system. The panel also agreed on a protocol for testing efficacy of canine plaque and calculus retardants, as well as adopting confidentiality and conflict-of-interest statements. Consultant panel members were polled on suggested names for the initiative with *Veterinary Oral Health Council* receiving the most votes.

The FDA's Center for Veterinary Medicine supported the establishment of a credible, independent review system for plaque and tartar retardation products, recognizing that it did not have the resources to review and regulate these products.

The AVDC Board of Directors endorsed the VOHC concept. An appointed committee was charged to develop a business plan and to establish operating procedures based on the work of the consultant panel. The AVDC adopted the committee recommendations in 1997, establishing the VOHC as an organization within AVDC.

### Evolution of the VOHC

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The first published testing protocol was for canine products that retard plaque mechanically and inhibit calculus mechanically or chemically. A protocol for feline products was added in 1998 and another for chemically active anti-plaque agents for dogs or cats was added in 1999. A formal policy on awarding the Seal to multiple products in a product line was adopted in 2003.

The first VOHC Seal of Acceptance was awarded in June 1998 to Hill's Pet Nutrition PRESCRIPTION DIET CANINE T/D. A full list of current VOHC-accepted products is available online at [www.vohc.org](http://www.vohc.org).

Use of the VOHC system is recognized worldwide. The following organizations have endorsed the VOHC Seal of Acceptance system:

- American Veterinary Dental College (AVDC), which owns and operates VOHC. AVDC also sponsors the annual Veterinary Dental Forum and is a sponsor of National Pet Dental Health Month in February.
- Academy of Veterinary Dentistry (AVD), an international group providing certification of training and knowledge in veterinary dentistry for veterinarians.
- American Veterinary Dental Society (AVDS), which publishes the quarterly *Journal of Veterinary Dentistry*. Membership is open to anyone with an interest in veterinary dentistry.
- Australian Veterinary Dental Society, an organization for veterinarians, dentists and other interested individuals in Australia.
- British Veterinary Dental Association (BVDA). Members are veterinarians, dentists and other individuals interested in veterinary dentistry based in the UK.
- European Veterinary Dental Society (EVDS). An organization for veterinarians, dentists and other interested individuals in Europe.

## VOHC Procedures and Protocols

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VOHC is not a regulatory agency. Submission of clinical trial results to VOHC is voluntary. If the data demonstrate required dental efficacy, the VOHC Seal of Acceptance is awarded to the product. As part of the submission, VOHC requires the company to assure that a product awarded the VOHC Seal is safe and meets all applicable regulatory requirements, and requires the company to inform VOHC of any problems with the product following issuance of the VOHC Seal.

The VOHC awards the Seal in two claim categories: “Helps Control Plaque” and “Helps Control Tartar.” If a product requests review for both, separate data sets and analysis summaries are required for each claim. Because good pet oral health depends on collaboration among the owner, the veterinarian and the pet, VOHC uses the familiar term *tartar* rather than the medical term *calculus* on the Seal.

Testing protocols include:

- General—general requirements applicable to all submissions
- Mechanical—additional requirements for products designed to mechanically retard plaque or calculus
- Chemical—additional requirements for products containing chemical anti-plaque and anti-calculus agent(s)
- Chemical Anti-Plaque—additional requirements for products containing a chemical anti-plaque agent



The general protocol requirements are:

**Two Trials.** The pets included in one trial cannot be included in the second trial. Additional study is required for products in a product line—such as the same product in different sizes, or products with a common anti-plaque or anti-calculus mechanism but different nutrient profiles.



**Protocol.** A protocol must be adopted before starting trials. VOHC does not require preapproval of the protocol but it is recommended. Parallel or cross-over trial designs are acceptable.

**Population.** Dogs or cats in trials must be similar in body weight, head type and age. General health must be assessed by physical examination, CBC, chemistry panel and urinalysis or assured by the veterinarian of record. Trials in dogs of different sizes are encouraged; the requirement for similarity of body weight in the two trials submitted to VOHC ensures statistical validation of the result.

**Use of Product.** The product is used in trials as recommended by the manufacturer on packaging and in product promotion.

**Control Diet.** Dogs or cats are fed a control diet in both the product and control groups or in the control group if the product is a diet that meets AAFCO nutritional standards. The control diet is a commercially available dry dog food or dry cat food that is fed dry and meets AAFCO requirements for all life stages.

**Teeth to be Scored.** All teeth listed below must be present and intact with normal occlusion for a dog or cat of that head shape. These teeth were selected on the basis of functional importance, likelihood of accumulation of plaque and calculus, likelihood of being present in the face of moderate periodontal disease and size for ease of recording. The buccal surfaces of the teeth on both sides of the mouth are scored unless a split-mouth study design is used for a trial as in, for example, a toothbrush.

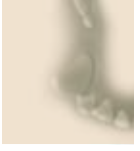
- Dog: Upper Jaw - I3, C, P3, P4, M1. Lower Jaw - C, P3, P4, M1.
- Cat: Upper Jaw - C, P3, P4. Lower Jaw - C, P3, P4, M1.

**Clean Tooth Model and Trial Periods.** Teeth are scaled and polished on day zero so that plaque and calculus scores are zero at the start of trial. Trials for plaque are at least seven days and trials for calculus, at least 21 days. Longer trials are encouraged; however, VOHC recognizes sufficient documentation to accept that differences obvious at one week for plaque and three weeks for calculus are indicative of longer-term clinical relevance and safety.

**Plaque Claim.** Standard plaque scoring indices can be used, although use of indices that divide teeth into segments is no longer permitted by VOHC, unless only the gingival half of the tooth is scored. A combination index incorporating extent of plaque coverage and thickness may be used. A novel plaque assessment method may be used but must be detailed and justified. Additional evaluation is required for products containing chemical anti-plaque agents or having a mechanical anti-plaque effect.

**Tartar (Calculus) Claim.** An index must be selected before the trial, used consistently, and calculus recorded after air-drying the tooth surface. A combination index incorporating the extent of calculus coverage and thickness may be used. Use of calculus indices that divide the tooth surface into segments is no longer permitted by VOHC. A novel calculus assessment method may be used but must be detailed and justified. Additional evaluation is required for products containing chemical anti-calculus agents or having a mechanical anti-calculus effect.

**Scoring.** Plaque and calculus indices are scored with the dog or cat under sedation or short-acting anesthesia. Use of justified indices that do not require anesthesia or sedation, such as the GCPI plaque scoring index (*J. Vet. Dent.*, Vol. 24, pp 14–20, 2007), is acceptable. Only trained, experienced scorers are to be used. The scores are to be “blinded” to the product and the same scorer must be used at each scoring episode in a trial.



**Randomization into Trial Groups.** Dogs or cats are to be assigned to product or control groups randomly. VOHC strongly recommends stratification before randomization to reduce variability between groups. There is no minimum required number of animals in each group. Full consideration of possible carry-over effects must be included in analyses of crossover design trials.

**Required Differences.** Currently, the minimum difference required between changes in the mean of all tested teeth for all animals in the group, comparing the product group with the control group, is 10% reduction in the plaque or calculus score in each trial, 20% for a product containing a chemical anti-plaque agent and a statistically significant difference ( $p < 0.05$ ) in each trial. Data are reported as means  $\pm$  standard deviation; statistical significance is determined using a two-tailed test. Changes to the mean percent required differences between control and active groups are under consideration by VOHC, as described in the News section of the December 2009 issue of the *Journal of Veterinary Dentistry*.

## Other Considerations

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Drugs or locally applied or lickable antiseptics other than the tested product may not be used for 14 days before trial begins, during the trial or during the rest period between trial legs in cross-over trials.

VOHC recognizes flexibility in measuring efficacy and will consider alternative, credible methods if the submitter provides detailed justification for new or non-referenced methods.

One of the most common reasons for concern about a submission is the failure to use and adequately describe appropriate study design and analysis procedures. The Council and its statistical consultant must clearly determine that VOHC statistical hurdles have been met. For this reason, VOHC strongly recommends that companies consult with a statistician in designing both the trial study and criteria for analysis.

In a marketplace cluttered with pet products claiming dental benefit, practitioners and pet owners can be assured that those carrying the VOHC Seal have proven efficacy. Recommending and/or dispensing products with this demonstrated result, used as directed, will help to reduce plaque and calculus build-up, the leading contributors to the development of periodontal disease.



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