



## Summary of Informal Discussion Following the VOHC Update Presentation at the Phoenix Veterinary Dental Forum, November 2018

Prepared by Colin Harvey, Director, VOHC

The PowerPoint slide set used in the formal VOHC Update presentation is attached.

At the end of the Digital Scoring part of the presentation, I requested a straw vote on whether to pursue development of the QLF software necessary to incorporate the intensity-thickness criterion as part of the QLF data read-out. The vast majority of people in the room indicated agreement with this by show of hands, with no negative votes or comments.

An open follow-up discussion took place immediately following the presentation, with a continuation of the open discussion the next day.

Here is a summary of the open discussion, which was attended by representatives of several companies that have products carrying the VOHC Seal, a representative of a lab animal facility where VOHC trials are conducted and a couple of VOHC Council members. This summary includes discussion and agreements reached at both sessions, edited for coherence of discussion of specific items. It also includes some follow-up comments and next step suggestions by Colin Harvey

1. **Proceed with QLF development.** The group unanimously agreed with the straw vote at the formal presentation that an extent of coverage/intensity-thickness QLF software package for use in scoring plaque and calculus in dogs and cats should be pursued.
2. **Disclosed vs undisclosed plaque.** It was agreed that the next step needs to be a decision on whether to use QLF images of disclosed or undisclosed teeth.
  - a. The consensus was to **lean towards undisclosed teeth**, as this may be more accurate in identifying plaque containing periodontopathogens vs thinner plaque of little clinical significance, but which does stain when disclosing solution is applied.
  - b. **Non-equivalence of data.** Based on data comparing disclosed and undisclosed QLF images provided by Waltham, it was recognized that QLF images of undisclosed teeth report a considerably higher % reduction in plaque than do disclosed images. Thus, if QLF images of undisclosed teeth are used as the data source supporting a VOHC claim, it is very likely that products that would not meet the current VOHC disclosed teeth minimum standard (20% reduction) might easily reach the 20% reduction standard when scored by undisclosed QLF. This would necessitate establishing a separate VOHC standard for data developed from QLF images of undisclosed teeth.
  - c. **Next Steps:** Waltham has provided some data on this topic. We are awaiting results of statistical analysis to be run at Waltham. These will be reviewed to determine whether to pursue undisclosed QLF images as the standard, and to determine whether the VOHC

standard would need to be revised for data produced using undisclosed QLF images. Any change in the VOHC standard, or adoption of a separate standard for use when QLF data are presented in the submission, would require wide-spread opportunity for discussion, with validation of the new undisclosed QLF standard as being equivalent to the current disclosed score obtained using subjective scoring system (Logan and Boyce; Warrick-Gorrel)

3. Other issues related to QLF image production and analysis:
  - a. **Additional comparative data.** The group agreed that it would be helpful in validating QLF if the QLF extent of coverage data would be compared with a Logan-Boyce score made from a printed QLF image, in addition to comparing it with the Logan-Boyce score from direct observation of the original tooth. **Next Step:** Is Waltham willing/able to do this? If not, would Waltham provide some images for others to do this?
  - b. The need to investigate whether products such as **tooth sealants (e.g. SANOS, OraVet Sealant) cause QLF fluorescence** of themselves was recognized, as this would significantly compromise the ability of QLF to reliably recognize plaque when these products are undergoing trials. **Next step:** Obtain samples of the sealants and apply them to teeth with and without plaque and calculus that will then be imaged for QLF. Does not require live animal teeth.
  - c. It was noted that **different substances fluoresce under different light wave lengths.** **Question for Inspektor:** Is the QLF blue light, which was developed for use in detecting incipient caries, the optimal light for identifying porphyrins produced by periodontopathogens and for identifying calculus that has been brushed free of surface plaque?
  - d. Adopting QLF as a recommended scoring system would require developing a **'Registration Format' for use when QLF images are obtained.** Items such as number of teeth to include in the QLF image, camera position including distance of the camera from the tooth surface and permitted extent of angulation beyond perpendicular to the tooth surface, ambient light in the scoring room. Are images taken at different camera angles to the tooth surface equivalent? It was recognized that taking images of individual teeth would take longer than a single image that includes all targeted teeth, which would likely have an effect on the ability to successfully complete the image-taking procedure in awake dogs and cats. There is also the question of whether the use of QLF images requires calibration of the QLF intensity of the clean tooth surface, as was done in the reported Waltham studies, to form the zero fluorescence score when calculating intensity of substrates on the tooth. **Next Steps:** Waltham has conducted some of the positioning and ambient light QLF tests – data to be reviewed if Waltham is willing to provide this; if these materials are insufficient for a systematic approach to examining these questions, this work will need to be done elsewhere. Request permission to use the Waltham QLF protocol as a draft for a VOHC QLF standard operating procedure document. Note: We are awaiting clarification from Waltham of the **Intellectual Property** status that arises from the Waltham patent that is currently under review by the patent authority; if a license is necessary, I have requested that this be in the form of a no-fee license when the proposed use is for a VOHC trial.

- e. **Should sedation be required?** It was recognized that reducing need for sedation or anesthesia is a high priority for most companies that participate in VOHC. Waltham has experience in conducting QLF scoring in awake, trained dogs. **Next step:** Request a summary from Waltham of the practicality of awake QLF scoring, including details of how to approach this.

#### 4. Inclusion of Calculus Scoring in the QLF procedure.

- a. It was agreed that the remaining substrate on the surface of a tooth that has been brushed can be assumed to be calculus. It is not clear whether the QLF fluorescence of brushed teeth produced during trials at Waltham represents porphyrins in plaque that is harbored in the crevices of brushed teeth, or the deposited calcium salts that form calculus, or something else.
- b. It was agreed that determining whether the QLF image is recording calculus should be investigated by applying the Schiff Calculus index (air-drying the tooth surface, with use of a sharp-tipped dental explorer to more accurately define the edge of the calculus) to a brushed tooth surface and comparing the mapped area to the area fluorescing in a QLF image of the same undisclosed brushed tooth surface. **Next step:** Comparison observations to be carried out. By whom and where? *Harvey may be able to do this using the Penn Vet Necropsy Room if I can obtain access to the QLF equipment.*

#### 5. Intensity Scoring as an indication of substrate (plaque or calculus) thickness.

- a. It was agreed that micro-sectioning and digital measurement of calibrated images of example areas of calculus-laden teeth, comparing the actual thickness to the QLF intensity in that area, would be a practical way to validate an assumption that QLF intensity does correlate with physical thickness. It was recognized that applying a similar process to validate plaque thickness would be more of a challenge because of the soft, amorphous nature of plaque. Perhaps try sectioning plaque on a frozen tooth? **Next step:** Take QLF images and then section the tooth surface before taking a macro image of the tooth section showing calculus depth, with a calibration ruler included in the image. Needs access to a facility that can conduct micro-sectioning of hard substances. *(Harvey may be able to arrange for this at the Penn Dental School).*
- b. The use of bands to score intensity of the fluorescence was agreed to be a viable option for use in programming software to produce a combination extent of coverage-thickness score for a tooth. Proposal 1 from Inspektor (three bands, to follow the three step observation scale in the Logan-Boyce and Warrick-Gorrel scores), was not considered to be of particular interest (except for investigating the correlation of L-B and QLF data) because of the wide range of intensity that would be represented in a particular band when the observation was limited to so few bands. **Next Steps:** It was agreed that Inspektor would be asked to develop software that would consist of six bands and 10 bands, to see if there is significant difference as a result of the reduction in the range of intensity within each band when the number of bands is increased.
- c. It was also agreed to ask Inspektor to develop software that simply reported the intensity of fluorescence of every pixel and then calculates a tooth score as the mean pixel intensity, which would be the ultimate method to limit variability in the measurement. **Next Step:** Request this from Inspektor.

**Comment from Colin Harvey after the open discussion sessions:**

Some of the '**Next Steps**' indicated above will require action by an individual or group that has access to a QLF camera. It was noted that the QRay Cam Pro, promised by Inspektor in 2019, sounds ideal for VOHC scoring purposes. Cost and availability to be determined in discussion with Inspektor. If the specific next steps cannot be done at a company that already has QLF equipment, one possibility would be for Summit Ridge Farms, which is not allied to any particular company but which has conducted many VOHC trials, to acquire a QRay Cam Pro that could be shared with Colin Harvey (who lives within driving distance of Summit Ridge Farms) for conducting tests and obtaining the samples suggested here, such as the QLF effect on Tooth Sealants now marketed for veterinary use, comparison of Schiff calculus extent vs QLF image data from undisclosed teeth, and micro-sectioning of tooth substrates to measure actual thickness.

### **The discussion then moved on to Other Topics:**

#### **Safety Testing:**

1. 'Digestibility/Solubility' Testing: There was consensus that the preferred term for the testing under discussion is In-vitro Solubility, rather than 'digestibility', to avoid confusion with the AAFCO Digestibility test (which requires sifting through feces to quantify the volume of undigested product).
2. Should VOHC be in the business of requiring tests designed to evaluate product safety (such as digestibility/solubility or mechanical testing)?
  - a. The group recognized that 'safety' was the remit of the FDA-CVM in the USA, and thus should not be a primary consideration for VOHC.
  - b. That said, Harvey noted that the AVDC Board is unlikely to accept that VOHC, and thus AVDC as the owner of VOHC, should completely divorce itself from considerations of safety; VOHC needs to ensure it has performed due diligence regarding safety when reviewing a VOHC submission.
  - c. It was noted that VOHC currently requires the company to state in an affidavit accompanying the submission that: *(Company) has complied with all safety and regulatory requirements in the jurisdictions where the product is marketed, that there is no information at the time of the VOHC submission that the product is unsafe, and that (company) will promptly inform VOHC of any reports or regulatory actions concerning the safety of the product.* It was agreed that an appropriate alternative to VOHC itself requiring specific solubility and mechanical tests and establishing standards would be for VOHC to revise the affidavit language to include: *For chew treats and large kibble products, provide a summary of any in-vitro solubility testing or mechanical testing that your company has conducted on this product to ensure safety of the product.*
  - d. It was recommended that the VOHC pre-trial protocol review includes a statement that the final submission is to include a summary of safety testing undertaken by the company, to give the company time to consider what, if any, safety testing should be done.
  - e. It was agreed that it would be useful for VOHC to **require** companies marketing chews or treats that carry the VOHC Seal that have a potential for obstruction to include the following language on the product package:

- i. *Be sure to select the correct size of (this product) for your dog.* This statement to be accompanied by a clearly-stated sentence or table that lists the product sizes and the body weight range of dogs that each size is recommended for.
- ii. Please observe your dog while it is chewing (the product), to ensure that the dog comfortably swallows it.
- iii. It was noted that some companies already do this, and that some flexibility in language or format may be needed because of the package design space limitations.

**Format of the VOHC Seal.**

1. Harvey noted that this had become the topic of considerable discussion as a result of the notification to companies in January 2018 that the VOHC Seal is to incorporate the VOHC website address, and that VOHC was going to be more vigilant in the future to ensure that the Seal was used consistently across all companies and all products. A major discussion point was how to incorporate foreign languages in the Seal to match specific market needs, being mindful of the space limitations in package design.
2. A compromise Seal has been proposed, which would retain the English-only ‘central’ part of the Seal (see the Seal at right), with the claim(s) (‘Helps Control Plaque’ and ‘Helps Control Calculus’ placed immediately below the central part of the Seal in whatever languages are required in that marketing area, and with the website address at the bottom of the Seal (second Seal at right).
3. Harvey noted that Canada is a case in point illustrating that this is not a simple matter. Companies had reported to him that they were required to provide both French and English versions of all text on all packages sold in Canada. He asked if anyone had information on the appropriate Canadian agency to contact for an official statement of government policy on this issue in Canada.
4. There is also the issue of certification mark registration. The VOHC Seal is a fully registered mark at the USPTO, but it is not registered in any other jurisdictions, which requires that the <sup>TM</sup> notation is used instead of the ® notation outside the USA. Preliminary information about making use of the Madrid Protocol has been obtained.



[www.VOHC.org](http://www.VOHC.org)

**Annual Reports:**

Harvey asked for input on how to ensure that the Annual Reports request is received and responded to by the appropriate individual, typically the individual or group that monitors consumer complaints and regulatory affairs. The Annual Reports are distributed each January in the letter that includes the invoice for the annual fee, which is typically sent to the financial management department of the company.

**Accepted Products List:**

Should the web version of the Accepted Products list be made available in different formats, such as by Company, by type of product (treat, diet, gel etc.), with separate links to each on the website?

### **Relationship with AAFCO:**

There was discussion of the relationship with AAFCO. Harvey noted that AAFCO did not approve a request from VOHC for recognition that the award of the VOHC Seal is sufficient evidence for AAFCO to accept a dental claim on a product that state Food Control regulators are reviewing. The AAFCO response was that doing so would create a precedent that could require AAFCO to accept similar findings from other entities that it does not control. It was suggested that VOHC visit with the National Animal Supplement Council (NASC) to obtain information on its status vis-à-vis AAFCO. Harvey noted that he had had a conversation with the President of NASC (which seems to have the kind of relationship with AAFCO that VOHC was proposing) at an AAFCO meeting in January 2018, and that the AVDC Board had approved appointment of an individual nominated by AAFCO to the VOHC Council if AAFCO approved the proposed relationship with VOHC.