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Director's Message



Cleaning up the Aloe vera industry - The IASC Certification Program

It's been nearly a year since I've joined the IASC as the Executive Director, and I have to say I'm pleased with the overall response and actions of this organization and its members in this time. Yes, we've got some very real and decidedly difficult challenges ahead, but we've also made some great strides for the membership and the industry as a whole.

We've gotten labeling guidance written and adopted, which will help us going forward in a number of ways, from avoiding misbranding concerns from the Food & Drug Administration (FDA) to getting our marketing and processing language and descriptions to be more accurate. We've begun work on an aloe vera juice monograph, which will provide standards for characterization, identity, and quality for the industry. We're soon to begin working on analysis of the retained sample from the NTP study, as well as the literature review portion of the risk analysis.

All-in-all, not a bad year one in the office, I'd say! But what I really want to mention here is that I heard the membership back in May of 2008, and wanted to let you know that we are working on keeping the certification program, and those illegally using the seal and language, as a top priority. To that end, I wanted to provide an update on the status of such affairs.

Lately, there have been many Cease & Desist letters sent out to various companies displaying the seal and language illegally. I am personally involved in initially contacting these companies and requesting they remove the seal and/or language from their materials/products, prior to referring them to counsel. In all cases, which recently totals over 15, we've managed to get these companies to remove the seal from their marketing and products - and in some cases we're getting them to join the program!

Some of these companies were brought to our attention from consumers asking questions about the program, and wanting to know if a particular product was certified, but many of them came from members and program participants who want to preserve the quality and sanctity of the seal and the program itself. We appreciate these efforts and hope you will

continue to inform us when you find websites, marketing materials, or products illegally utilizing the seal and language.

Keep in mind, only those participants in the program, meaning those companies who have paid to have their products tested and facilities audited, are eligible to display the seal and related language. Companies who state they "use IASC certified raw materials", but are not actively participating in the program, are doing those of you who are a disservice, and I again congratulate you all on your insistence that these companies join the program or stop the illegal usage of the certification program for their own benefit.

We will continue to keep the seal program and illegal usage as a priority and again hope you will help us to do so, and make sure the IASC certification program operates as the highest standard of quality and purity in the aloe vera industry.



Devon Powell
Executive Director

YUN-HO LEE AWARDS



IASC Announces Winners of 9th Annual Yun-Ho Lee Award for Scientific Merit

The International Aloe Science Council (IASC) was honored to present the 9th Annual Yun-Ho Lee Award for Scientific Merit to the following researchers for their significant contributions to scientific information on aloe:

For the cultivation and analysis of 21 Aloe vera ecotypes and identification of the ones most suitable for gel and latex yield: Alagaukannan G, Ganesh S, Gopal SK. Ascertaining genetic variability in Aloe vera L. for growth, yield and quality. Faculty of Agriculture, Gandhigram Rural University, Gandhigram 624 302, Dindigul District, Tamil Nadu, India. July 2008. The results of Alagaukannan et al.'s research are potentially useful for growers wanting to supply industry with aloe materials for cosmetics, food, or drug uses.

For demonstrating the glucose lowering activity of aloe vera gel and powder enriched with aloe chromones isolated from Aloe ferox leaves in a mouse model: Yimam MA, Zhao J, Zhao Y, Foo J, Hong M, Hanna B, Judah N, Jia Q. Aloe chromones improve insulin sensitivity by increase of adiponectin level and their potential in maintaining healthy blood glucose levels. Unigen Pharmaceuticals, Lacey, WA, USA. The research of Yimam et al. suggests a potential for aloe in treatments for diabetes and metabolic syndrome.

"The Council received many excellent nominations, and we are pleased to recognize outstanding scientific contributions in two distinct fields of aloeresearch this year - agriculture and pharmacology" said Executive Director Devon Powell. "The research on aloe continues to grow, and IASC thanks the award winners and nominees for their good work."

The Yun-Ho Lee Award for Scientific Merit is named in honor of Aloecorp-founder and former-

GUEST ARTICLE



Literature Review: Analytical Methods for Aloe

By Steven Dentali, Ph.D., Chief Science Officer, AHPA, & Scientific Advisor, IASC

A recent article on a comparative analysis by HPLC (high performance liquid chromatography) and TLC (thin layer chromatography) of aloin content in herbal materials containing *Aloe vera* dried latex purchased in Mexico raised questions concerning the relative value of using TLC vs. HPLC. Consequently, I decided to present relatively recent work regarding TLC of botanical materials and to review this specific paper thereby helping to provide an introduction to using TLC in botanical analysis. I will start with a reprinted literature citation review from the March 2008 *AHPA Report* (Vol. 23, No. 3, p. 18-19).

TLC in QC: use it if you can (assuming you need it)!

Evaluation of thin-layer chromatography methods for quality control of commercial products containing *Aesculus hippocastanum*, *Turnera diffusa*, *Matricaria recutita*, *Passiflora incarnata*, and *Tilia occidentalis*. Ramírez-Durón R, Cenicerros-Almaguer L, Salazar-Aranda R, Salazar-Cavazos Mde L, Waksman de Torres N. *J AOAC Int.* 2007 Jul-Aug;90(4):920-4.

Thin layer chromatography (TLC) is a chromatography technique used to separate mixtures. Thin layer chromatography is performed on a sheet of glass, plastic, or aluminum foil, which is coated with a thin layer of adsorbent material, usually silica gel, aluminium oxide, or cellulose. This layer of adsorbent is known as the stationary phase. (follow this link for more information on TLC from Wikipedia:

http://en.wikipedia.org/wiki/Thin_layer_chromatography)

One very useful technique of quality control testing, including identity tests, is thin-layer chromatography (TLC). As stated in the abstract of this paper these "methods are simple, sensitive, and specific and can be used for routine quality control of raw herbals and formulations ... (they are) simple and reliable analytical methods that can be performed in any laboratory for the purpose of quality control of dietary supplements or commercial herbal products..." I don't tout TLC just because it makes Eike Reich of American Herbal Products Association (AHPA) member company CAMAG happy (CAMAG made the TLC equipment used in this study). It's a technique that I applied on a daily basis as a student of natural products chemistry. It's a stunningly versatile tool that should see wider use in our industry, and in my opinion, ahead of all other simple tools sold for quality control in a botanical laboratory (where appropriate, of course).

One reason for the need to implement this technique is because what often needs to be measured is not simply a single compound, but the totality of an extract. As the authors state (and AHPA technical committees have often repeated), often times "the entire herbal drug or commercial herbal preparation is regarded as the active substance, regardless of whether constituents with defined therapeutic activity are known." While we may reasonably disagree with the authors definition of a standardized extract as "an extract obtained from an authenticated specimen of the plant under consideration, whose content in active substances and/or markers is known" (a very common misperception), this paper remains as a lucid description of the need for TLC and its fundamental utility for characterization and quality

tests, including stability, of botanical raw materials.

This is a well written, informative paper that employs TLC in a practical application for the testing of marketplace materials purported to be made from *Aesculus hippocastanum*, *Turnera diffusa*, *Matricaria recutita*, *Passiflora incarnata*, and *Tilia occidentalis* known as horse chestnut, damiana, chamomile, passion flower, and tilia, and as castaño de indias, damiana, manzanilla, flor de la pasión, and tila, respectively, in Mexico. While there was varying success in matching the commercial samples with the selected control materials, the utility of obtaining consistent patterns by TLC in a quality control setting should be immediately apparent to anyone who reads this paper. I think it's an excellent, accessible demonstration of TLC for companies that sell botanical materials, and not just because I'm the chair of the editorial board of the organization that published the paper!

Validated HPLC method for anthraquinone analysis of Aloe vera juice

Determination of the anthraquinones aloe-emodin and aloin-A by liquid chromatography with mass spectrometric and diode array detection. Elsohly MA, Gul W, Avula B, Khan IA. *J AOAC Int.* 2007 Jan-Feb;90(1):28-42.

High-performance liquid chromatography (HPLC) is a form of column chromatography used frequently in biochemistry and analytical chemistry to separate, identify, and quantify compounds. HPLC utilizes a column that holds chromatographic packing material (stationary phase), a pump that moves the mobile phase(s) through the column, and a detector that shows the retention times of the molecules. Retention time varies depending on the interactions between the stationary phase, the molecules being analyzed, and the solvent(s) used. (For more information on HPLC follow this link to Wikipedia: <http://en.wikipedia.org/wiki/HPLC>)

This paper investigated HPLC methods to determine low levels of two anthraquinones in several commercial aloe-based products. Results using a very specific and sensitive detector, MS or mass spectrometry, were compared to those obtained with a less specific and less sensitive diode array detector operating in the ultraviolet (UV) frequency range. UV detectors are commonly employed in analytical laboratories with MS less commonly seen. This paper showed that HPLC-UV, while less sensitive and specific, could be used instead of HPLC-MS for the task at hand.

Calibration plots were created for the two standards and the limit of detection (LOD) and limit of quantitation (LOQ) determined for each method. Accuracy and precision for each method over the course of a day and between days was determined as was recovery (extraction efficiency) data, which is the percent of compound that can be measured when experimentally extracted from a test sample. This work is exemplary of standards to be applied in order to validate methods of analysis. It is instructive to review published FDA guidance on this topic that appeared on the March 1, 1995 *Federal Register*, pages 11259-11262 (contact the IASC office if you need help accessing this document). FDA also has published a more extensive guidance on analytical validation in May of 2001 that can be found at <http://www.fda.gov/cder/guidance/4252fnl.htm> (accessed May 13, 2009).

Once these methods were validated, meaning they were determined to be fit for purpose, they were used to analyze 53 samples of liquid products and 30 solid or semi-solid products. Only 2 of the liquid products were found to contain greater than 1 ppm of either anthraquinone, aloe-emodin in each case, while the solid and semi-solid products were shown to contain predictably higher amounts of anthraquinones. In these cases the amount of aloin-A, with few exceptions, was considerably higher than aloe-emodin and ranged from not detected to over 300 ppm. The authors stated that "most solid and semisolid products contained >1 ppm of either anthraquinone with 11 out of 30 samples containing \geq 10 ppm of

one or both analytes." (A peak for aloin-B was observed but not measured.)

The results obtained between the methods were well correlated indicating that the methods were equally acceptable for this work. The low levels in the liquid products were thought to be due to their very dilute presence or from instability in solution. Further work is planned to determine which of these factors accounts for the observed result.

What about HP-TLC instead? You may want to use it if you can.

Comparison of high-performance liquid chromatographic and thin-layer chromatographic methods for determination of aloin in herbal products containing Aloe vera. Ramírez Durón R, Cenicerós Almaguer L, Cavazos Rocha NC, Silva Flores PG, De Torres NW. *J AOAC Int.* 2008 Nov-Dec;91(6):1265-70.

This paper performed a validation protocol for a TLC method that included measurements of selectivity, detection limit, precision, and robustness, and one for HPLC that consisted of linearity, detection and quantitation limit, precision, and recovery. Twelve commercial aloe latex products were analyzed by each method. The results between the methods were comparable though the TLC results were semi-quantitative and all results were in the parts per thousand range (mg/g).

This paper appears to have an error in the reported limit of detection by TLC. Half the amount reported for the limit of detection can be clearly seen in a reproduced figure (an email has been sent to the author to discuss this concern). This aside, if the limit of detection of aloin is sufficiently low by TLC then it may be possible to use this simple tool as an inexpensive alternative to HPLC depending on the task at hand. TLC has the added benefit over HPLC of providing qualitative information that can be examined with the naked eye for any apparent substantial changes batch to batch. The folks at CAMAG have published an article on validation of HPTLC (high performance TLC) for QC and stability testing for herbals, and one on validation of botanical identity in a cGMP setting. This latter paper is accompanied by supplementary information. The citations are as follows.

Validation of standardized high-performance thin-layer chromatographic methods for quality control and stability testing of herbals. Koll K, Reich E, Blatter A, Veit M. *J AOAC Int.* 2003 Sep-Oct;86(5):909-15.

Validation of high-performance thin-layer chromatographic methods for the identification of botanicals in a cGMP environment. Reich E, Schibli A, DeBatt A. *J AOAC Int.* 2008 Jan-Feb;91(1):13-20. (Supplemental information, supplement pages 1-388.)

I continue to encourage all botanical laboratories to be familiar with TLC because, depending on the task, it fits many purposes. Anyone who has used TLC understands its relative utility and the jobs it may be suited for. I continue to be a strong advocate for comprehending botanical ingredient quality from agricultural practices to finished product manufacturing. TLC is not a tool that should be overlooked; it should be recognized as an important component in all botanical laboratories engaged in analytical work. In fact a basic research botanical laboratory could not operate without it.

You may have noticed thrown in to the discussion here were issues of validation. Basic botanical research laboratories can and do often function without any concept of validating an analytical method because they are involved in basic research, not the use of methods that are expected to get the right number from an analytical method every time regardless of who is conducting the analysis and what lab they are in. If your business depends on the reporting of numbers from analytical methods then those methods need to be validated for their use; they must be shown to be fit for purpose.

Steven Dentali, PhD, is Chief Science Officer at the American Herbal Products Association (AHPA) where his duties include helping to set quality standards for the botanical products industry and providing guidance and advice to AHPA member companies, related organizations, government agencies, scientific publications, and the popular press. He is a United States Pharmacopoeia Convention Delegate and a member of the USP Committee of Experts, Dietary Supplements - General Chapters. He is also Editorial Board Chair of AOAC and Secretary of the AOAC Presidential Task Force on Dietary Supplements, and an advisory board member of the American Botanical Council and the American Herbal Pharmacopoeia.

Ullman Shapiro & Ullman INSIDE LAW

Using Copyright Law to Protect Your Products

By Charles H. Knull, Esq.

Protecting the integrity of your aloe based products requires careful attention to the protection available under U.S. copyright laws. The Federal Copyright Act protects the "original expression" of an idea or ideas when such expression is "fixed", that is, when it is printed, painted, recorded, filmed or otherwise set down. The ideas themselves are not protected by copyright.

Anybody making or marketing consumer products must seriously consider registering copyrighted material such as the text and illustrations of a web site or of print advertising, tapes of infomercial recordings, the labels on the goods and its packaging, and any instructional or informational material packed with products or offered as handouts. While simple labels may not qualify for copyright protection, an aloe product label containing illustrations and original text should be subject to such protection.

A copyright is a "bundle of rights." The owner of a copyright has the right to prevent (by injunction) others from copying, distributing, making materials based upon the copyrighted work, and otherwise using the copyrighted material. If the copyright owner has made a timely filing of an application for registration of the material with the U.S. Copyright Office, the copyright owner can also recover "statutory damages" (in practice, a form of punitive damages) and its own attorney fees from the infringer. Thus, as a simple infringement might not carry much in the way of monetary damages with it, a person who makes timely registrations of its material can make it extraordinarily costly for anyone to copy such material.

EXAMPLE A: Ajax Aloe Products Company owns the trademark registration for AJAX ALOE SUPREME for a calcium/aloe dietary supplement. It has also registered the box design and the product information sheet of its product at the U.S. Copyright Office. Zebra Aloe Supply, known for its knock-offs, soon after comes out with a calcium/aloe supplement that it claims is "comparable to AJAX ALOE SUPREME". But Zebra not only compares, which can be permissible, but also copies the text of Ajax's product information sheet inserted in the product box. A court finds that using "comparable to AJAX ALOE SUPREME is permitted under principals of comparative advertising. But it further finds that the product information sheet was a copyright infringement, and awards the owner of AJAX ALOE SUPREME statutory copyright infringement damages of \$100,000 plus its attorney fees.

EXAMPLE B: Same situation as example A, but Ajax has not timely registered its copyright. All the Court can award in this situation is actual damages of \$100 for the cost of the infringing

information sheets. Since Ajax also loses on its comparative advertising claim, its award of \$100 hardly compares to the \$150,000 it spent on litigating the matter.

Since people bent on borrowing a company's good will by trading on trademarks ordinarily care little about also borrowing packaging, web site text, or instructional inserts, having registered copyrights, combined with a trademark infringement suit, can obliterate such an infringer. An application for copyright registration is a simple document to complete and the government filing fee is only \$45.00. Few protective actions are as cost-effective and simple to do.

EXAMPLE C: Humongous Aloe Corp, an aloe product distributor, finds that a website of a competitor has taken both photographs and text from its website and used it on its own. Humongous had dutifully taken out a copyright registration for the website before it was copied. The defendant distributor claims that its web designer took the material without its knowledge. In the ensuing law suit, the distributor is ordered to pay \$50,000 in statutory damages for copying the materials, plus Humongous's legal fees for bringing the suit. Ignorance is no defense to copyright infringement.

Registering Copyrights with Customs

Customs Watch Registration. A company that copyrights its product packaging can record the registrations with U.S. Customs and impede entry of unauthorized goods from overseas which are in the same or similar packaging. This is useful to the Aloe manufacturer who has exclusive distribution deals in the United States and which also sells overseas, perhaps at reduced rates. The goods coming into the country, commonly called gray market, may violate the distribution right under copyright, which says that the owner of a copyrighted work can control where the goods are distributed. While a rogue distributor may thwart the manufacturer's plans by selling where it is not authorized to sell, the combination of the copyright and customs watch can assist in cutting off entry of the goods which are likely to interfere with US distributor relations.

Conclusion

Makers of nutritional products invest in marketing and advertising in order to set their products apart from other products. It is penny wise and pound foolish not to reinforce this investment by taking the necessary steps to protect copyrights that are the by-product of such marketing and advertising. Much of the clout in copyright law comes from early filing and registration.

"Inside Law" is an "Inside Aloe: Online" exclusive column by IASC General Counsel Ullman, Shapiro and Ullman.

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Ullman, Shapiro & Ullman attorneys have long established nationwide reputations in the areas of Food and Drug Law, Intellectual Property and Trade Regulation Litigation.

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IASC members receive a 10% discount

IASC LABELING GUIDANCE

IASC Board Approves New Labeling Guidance for Aloe Products, Use of Term 'Whole Leaf'; Members Must Comply By March 2010

The International Aloe Science Council (IASC) Board of Directors voted March 9 to adopt guidance on the labeling and marketing of Aloe vera products and the use of the term "whole leaf." A working group of the council's Regulatory Affairs Committee developed the guidance in an effort to reduce consumer and regulatory confusion and avoid unnecessary enforcement actions against marketers following a meeting with the FDA in which it was relayed that products labeled as "whole leaf" could be considered misbranded (as the product literally does not contain the "whole" leaf), as well as the future release of a National Toxicology Program (NTP) study on the long-term oral use of "whole leaf *Aloe vera* extract"[1]. The guidance requires label changes for those products marketed in the U.S. and is recommended for products for sale globally.

The guidance for the use of the term "whole leaf" in product labeling and marketing is two-fold:

1. The guidance requires IASC members to cease the usage of the term "whole leaf" without further clarifying language to identify the processing of the ingredient. Products produced by initially grinding the entire leaf must, under the new guidance, add to the term "whole leaf" appropriate descriptive language to further identify that certain components have been removed, such as "De-colored"; "Active charcoal-filtered"; "Filtered," etc. It is up to each individual company to determine the best terminology to use to describe their processes.
2. While not required, the guidance recommends members cease usage of the term "whole leaf" entirely in order to avoid all issues and concerns likely to be raised from the NTP study.

The required addition of descriptive language to labels to further identify the processing of such products (e.g., De-colored whole leaf; Active charcoal filtered whole leaf; Filtered

whole leaf, etc.) will avoid a literal translation of the term "whole leaf" and likely satisfy FDA concerns regarding misbranding. However, such products will still be subject to scrutiny upon release of the NTP study, and as mentioned above, will likely become targets of legal (and possible enforcement) action, especially Proposition 65 lawsuits in California. For this reason, the IASC labeling guidance strongly recommends the complete cessation of the usage of the term "whole leaf".

"IASC is sensitive to the fact that the 'whole leaf' market represents a significant share of the aloe industry and that the adoption of such a position will likely create difficulties for many companies and their revenues," said Executive Director Devon Powell. "However, a proactive response; consistency among raw materials suppliers and manufacturers; and a strong PR push by the industry may potentially alleviate long-term market-share loss, and will more than likely prevent potential damage, including legal and enforcement actions."

Terminology & Other Requirements

To address U.S. regulatory concerns regarding a lack of standardization in the identification of aloe ingredients, the adopted document requires IASC members, and recommends the global aloe industry, comply with the definitions identified in the IASC document "Definitions of Terms Commonly Used in Aloe Industry," in so far as those terms are included in the document, for all terms used in the marketing and labeling of aloe vera products. All products marketed for sale in the U.S. must be labeled with the Latin binomial *Aloe vera*; the Standard Common name (SCN) "aloe vera," and identify the plant part used (i.e., leaf, inner leaf, aloe latex). This is also recommended for products for sale globally for labeling standardization.

With regards to the labeling of concentrated Aloe vera products and aloe products in liquid form, the document provides guidance on the declaration of the percentage of juice, reconstitution and quantitative concentration. Also in compliance with the Federal Food Drug and Cosmetic Act (FFDCA), the guidance requires conventional foods and beverages bear a Nutritional Facts panel and dietary supplement products are labeled with a Supplement Facts panel.

Members have until March 9, 2010 to come into compliance with the newly adopted labeling guidance, but it is recommended that manufacturers consider making label changes as quickly as possible, as the exact date of the NTP study release is unknown.

"While the concerns facing the aloe industry are serious, I am confident that we can effectively address these issues and that IASC member companies can continue providing health-promoting internal-use Aloe vera products to consumers," Powell said.

The complete guidance for industry, including the "Definitions of Terms Commonly Used in The Aloe Industry" is available here:

http://www.iasc.org/09_0309_IASC_labelingguidance.pdf.

[1] See the February 2009 issue of *Inside Aloe Online* for more information on the NTP study and IASC's meeting with FDA staff: <http://www.iasc.org/February2009.pdf>.

THE SCIENCE OF ALOE - Recently Published Studies

- [Protective effect of Aloe vera on polymicrobial sepsis in mice.](#)
- [Separation and purification of aloe polysaccharides by a combination of membrane](#)

[ultrafiltration and aqueous two-phase extraction.](#)

- [Ultrasonic extraction and HPLC determination of anthraquinones, aloe-emodine, emodine, rheine, chrysophanol and physcione, in roots of Polygoni multiflori.](#)
- [Promotion proliferation effect of a polysaccharide from Aloe Barbadensis Miller on human fibroblasts in vitro.](#)
- [Evaluation of aloin and aloe-emodin as anti-inflammatory agents in aloe by using murine macrophages.](#)
- [Inhibition of infectious diseases by components from Aloe vera.](#)
- [Novel type III polyketide synthases from Aloe arborescens.](#)
- [In vitro evaluation of UV opacity potential of Aloe vera L. gel from different germplasm.](#)
- [Hypoglycemic and hypolipidemic effects of processed Aloe vera gel in a mouse model of non-insulin-dependent diabetes mellitus.](#)
- [Investigations of Free Anthraquinones from Rhubarb Against alpha-Naphthylisothiocyanate-induced Cholestatic Liver Injury in Rats.](#)
- [Preliminary study of effectiveness of aloe vera in scabies treatment.](#)
- [Antibacterial Activities of Crude Extract of Aloe barbadensis to Clinically Isolated Bacterial Pathogens.](#)
- [Antibacterial Activities of Crude Extract of Aloe barbadensis to Clinically Isolated Bacterial Pathogens.](#)
- [A Novel Liquid Multi-Phytonutrient Supplement Demonstrates DNA-Protective Effects.](#)
- [Effects of the application of Aloe vera \(L.\) and microcurrent on the healing of wounds surgically induced in Wistar rats.](#)
- [Structure-activity relationships of anthraquinones on the suppression of DNA-binding activity of the aryl hydrocarbon receptor induced by 2,3,7,8-tetrachlorodibenzo-p-dioxin.](#)
- [Intestinal Drug Transport Enhancement by Aloe vera.](#)

ALOE MONOGRAPH & RISK ASSESSMENT

IASC Board Authorizes Special Assessment to Finance *Aloe vera* Risk Assessment, Monograph Development

To protect the trade of *Aloe vera* products, the Board of Directors of the International Aloe Science Council (IASC) voted March 9 to finance the urgent execution of a toxicological risk assessment and the development of a critical quality standard monograph for *Aloe vera*.

"The IASC Board of Directors has shown remarkable leadership in its response to the threats facing the aloe industry," said Executive Director Devon Powell. "The targeted actions endorsed by the Board are cost-effective and preventative, and we trust all members understand the necessity and time-sensitive nature of these actions and the special assessment. Only with the immediate financial support of the membership will the IASC be able to adequately develop responses to the concerns posed by the FDA and NTP study."

The need for such action follows IASC's recent awareness of significant concerns the U.S. Food and Drug Administration (FDA) holds in relation to commercial *Aloe vera* products based on a currently unpublished two-year National Toxicology Program (NTP) study on *Aloe Vera* (See the February 2009 Inside Aloe Online for more information). A risk assessment will put the findings of the NTP study into context for the consideration of regulators, such as California's Office of Environmental Health Hazard Assessment (OEHHA). The monograph should help allay the concerns of FDA.

The Board's decision to finance a risk assessment and the development of a monograph is based on the Council's extensive consultation with experts in toxicology, food and drug law and California's Proposition 65. It is clear to IASC that the failure to take proactive measures at this time would likely have a substantial and detrimental impact on the aloe industry. Namely, marketers and manufacturers of products containing *Aloe vera* would likely face enforcement action by FDA, lawsuits under Proposition 65 and significant negative media attention.

In order to raise funds for these trade-protecting projects, IASC's Board of Directors authorized a special assessment of the membership in the amount of 60% of each members dues level. The Board, being sensitive to company size, and the current economic climate, established the assessment as a percentage of dues in order to more fairly distribute the costs amongst the membership.

"It's also important to note that this initial activity approved by the board will likely not be enough to keep the industry out of the crosshairs of the enforcement agencies and consumer population at-large should negative results be published from the NTP study," Powell further noted. "More work will need to be done - such as characterization of the retained samples utilized in the study when we are able to obtain them - which will help differentiate the samples used in the study from products currently on the market. This will also require funding assistance as well as direct participatory support from the membership in order to complete".

Members with questions or concerns related to the special assessment fee, NTP study, risk assessment and monograph are encouraged to contact Devon Powell (dpowell@iasc.org; (301) 588-2420). IASC member companies will receive more detailed information on the special assessment fee shortly. Additional information on the risk assessment and monograph is below.

Risk Assessment

A risk assessment is a process by which scientists evaluate the potential for adverse health or environmental effects from exposure to naturally occurring or synthetic agents. The goal of a risk assessment is to provide risk managers, such as government regulatory officials, with a

rational basis for making decisions about managing the use of chemicals or physical agents in order to protect health and environment.

Two-year studies in laboratory rodents, such as the bioassay study conducted by NTP on *Aloe vera*, provide preliminary data that serve to identify chemicals or physical agents having the potential to be hazardous to humans. These data are a component of a risk assessment. They are used in the hazard identification stage, which is an evaluation of the adverse effects the agent is capable of causing.

A complete risk assessment includes a dose-response assessment, exposure assessment and risk characterization. These additional components serve put the adverse effects the agent is capable of causing into a broader context: How much of an agent is required to cause a toxic effect? How much are people exposed to? Overall, what is the likelihood that, for example, that there will be an increase in cancer in a population exposed to an agent?

IASC has engaged NSF International's Toxicology Group to conduct a risk assessment. NSF is an internationally-respected organization. Based on this and a review of several bids from other groups, IASC is confident in the expertise and experience of NSF. To learn more about the Toxicology Group [click here](#).

Monograph Development

Currently, the non-pharmaceutical aloe industry lacks a strong quality standard monographs for *Aloe vera* that includes such elements as processing procedures, standards for manufacturing (e.g., aloin limits) and other information. IASC has engaged the American Herbal Pharmacopoeia (AHP) to complete a monograph for *Aloe vera*.

The goal of the AHP Compliance Monograph is two-fold: (1) to develop multiple methods of identification and characterization of authenticated *Aloe vera* and (2) to develop standards of purity with an appropriate analytical method (HPLC) for detecting anthraquinone aloin down to 10 parts per million (ppm) in raw material and finished product.

The AHP relies on industry for technical expertise, and seeks the following from IASC members:

- Copies of published or non-proprietary data pertaining to quality control and testing
- Samples from various growers - for the purpose of macroscopic, organoleptic, microscopic and chemical characterization
- Any existing macroscopic and microscopic characterizations
- Any existing HPLC methodologies for detecting anthraquinone aloin down to 10 ppm in raw material and finished product
- Finished product samples - to determine if the analytical method is appropriate for obtaining the desired analytical quantization
- Experts for the review process
- Photographs of *Aloe vera* in its various forms including: different varieties; flowering; fruiting; close-up of various plant parts; photographs of commercial fields; drying processing; extraction equipment if appropriate

To contribute to the development of the monograph or learn more about the process, contact Devon Powell.

Devon Powell
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LITERATURE REQUEST

IASC Solicits Studies for the Risk Assessment Literature Review

IASC requests the assistance of the membership in compiling studies for the literature review begun by NSF International's Toxicology Group. The literature review is the first step in the recently-announced member-funded risk assessment of aloe vera materials. If you have studies or other information that you feel are relevant to the biological activity and toxicology of aloe vera gel and juices, including company data, then please send them to Executive Director Devon Powell (dpowell@iasc.org):

International Aloe Science Council
8630 Fenton Street
Suite 918
Silver Spring, MD 20910

Especially useful will be clinical studies, in vitro studies, and any other data that will aid in determining safe use of aloe vera materials. Studies are only useful if it can be determined exactly what was tested, therefore studies where the study material is well described - including dose - are likely to be of most use.

"The response from IASC members following recent news has been very encouraging," said IASC Executive Director Devon Powell. "Clearly, this industry understands that IASC's actions can only be as strong as the contributions and efforts of our members, and we look forward to receiving the studies we need to make the literature review portion of the risk assessment the best possible reflection of the current science on Aloe vera."

More information on the risk assessment is available in the March 18, 2009 IASC Member Update, "IASC Board Authorizes Special Assessment to Finance Aloe vera Risk Assessment, Monograph Development," and the [February 2009 issue of Inside Aloe Online](#). Additionally, members are always encouraged to contact Devon Powell with any questions or concerns.

BOARD OF DIRECTOR ELECTIONS



IASC Announces Newly Elected Officers, Members of the Board of Directors

The IASC Board of Directors welcomes four new members to its ranks and congratulates its newly elected officers: President-Elect Chris Hardy of Aloe Vera of America/Forever Living Products; Secretary Chris Clarke of Winning Solutions/Miracle of Aloe; and Treasurer Tom Brown of Florida Food Products.

Candidates for the four open seats on the Board of Directors were nominated during the March 9 Board of Director's meeting to fill vacated seats and elected by the current Board per the IASC by-laws. Please join the IASC in welcoming and congratulating the following new

Board members:

K.S. Yoon, President & CEO, Aloecorp

Mr. Yoon started as President and CEO of Aloecorp in 2008, bringing with him a decade's worth of executive experience, substantial management and leadership skills and knowledge of the financial industry. Prior to joining Aloecorp, Mr. Yoon was Executive Vice President and Chief Strategy Officer for ECONET, Inc. He thrives in challenging, high energy start-up ventures, turnarounds and high-growth organizations and is characterized as a talented strategist, capital thought producer, communicator, and project leader. Mr. Yoon holds an MBA from Korea University in Seoul, Korea.

Wenwen Ma, Ph.D., Vice President of Quality, Unigen Global

Dr. Ma joined Unigen, Inc in 2004 as Director of Quality Control and Quality Assurance and quickly worked her way up to VP-Quality for Unigen Global, overseeing the quality system of Unigen US and Unigen Korea for testing and release of raw material and final dietary ingredients, specification, quality complaints, quality policies, vendor qualification and GMP implementation. Dr. Ma has a Ph.D. in Natural Products Chemistry from Purdue University and nearly 20 years of professional experience in QC/QA in the pharmaceutical and natural products industries. She is a member of the American Society of Pharmacognosy and AOAC International and has published widely.

Charlie Metcalfe, Founder and Chief Science Officer, Custom Analytics

Mr. Metcalfe founded Custom Analytics, a contract analytical laboratory located in South Carolina, in 1998. The company performs analyses for the pharmaceutical, personal care and nutraceutical industries; specializing in method development and optimization. Mr. Metcalfe holds a B.Sc. in Chemistry from Virginia Tech with graduate studies in Biomedicine at the University of Tennessee and Radiochemistry at the University of Nebraska. A member of the IASC since 2004, he brings an interest and enthusiasm in improving upon the methodology used for characterization and standardization protocols for aloe raw materials and products.

Santiago Rodriguez, Ph.D, CEO & Technical Director, Lorand Laboratories

Aloe vera has been at the center of Dr. Rodriguez's professional life for nearly two decades. CEO & Technical Director for Lorand Laboratories since 2001, Dr. Rodriguez has also worked as a consultant to aloe companies across the globe and previously worked for Carrington Laboratories as director of research. As a consultant, Dr. Rodriguez has been involved in such works as overseeing the design and construction of several processing plants, developing manufacturing technology and assisting with process improvement and quality assurance. He has contributed to the work of the IASC for several years and has been a validation inspector for the Council since 2005. Dr. Rodriguez holds a Ph.D. in chemistry from the University of Texas.

"The Officers of the Board of Directors and the new members of the Board bring a wealth of experience and will no doubt contribute greatly to the excellent work of this group of leaders," said Executive Director Devon Powell. "I look forward to continuing ongoing work and beginning new projects with these outstanding individuals."

The complete Board of Directors for 2009-2010:

Walt Jones, Chairman of the Board

Ken Jones, President (Aloecorp)

Chris Hardy, President-Elect (Forever Living Products/AVOA)

Tom Brown, Treasurer (Florida Food Products)

Chris Clarke, Secretary (Winning Solutions/Miracle of Aloe)

Mick Anderson (Aloecorp)

Jess Clarke, Jr. (Winning Solutions/Miracle of Aloe)

Jesper Hummeluhr (Aloe Vera Group)
Qi Jia (Unigen Pharmaceuticals)
Dr. Yu Jian (Ministry of Science, P.R. China - Honorary)
Sabine Larsen (LR Health & Beauty Systems)
B. William Lee (Univera - Emeritus)
Don Lovelace (Lily of the Desert)
Dr. Wenwen Ma (Unigen Global)
Rex Maughan (Forever Living Products - Emeritus)
Charlie Metcalfe (Custom Analytics)
Bahn Phan (Forever Living Products/AVOA)
Bill Pine (Improve USA)
Roger Poore (Forever Living Products/AVOA)
John Price (Royal Body Care)
Dr. Santiago Rodriguez (Lorand Laboratories)
Don Smothers (Naturetech)
K.S. Yoon (Aloecorp)

ALOE IN THE NEWS



[Development: Make Use of African Skills - Inter Press Service News Agency](#), May 4, 2009

[Skin Care News: Aloe - Allure](#), April 13, 2009

[Top 10 Ingredients to Look for in a Cleansing Program - The Examiner](#), April 8, 2009

[The Healing Plant - The Baltimore Sun](#), April 2, 2009

[Home Remedies: What Works and What Doesn't - The State Journal-Register](#), March 2, 2009

WORKING GROUPS

Help IASC Work for You: Join a Working Group Today

Working groups on by-laws, level of service under new management solicit members

IASC is soliciting members for two working groups established at the most recent meeting of the Board of Directors. The first working group is tasked with conducting a review and revision of IASC's by-laws. The second working group will conduct a review of the level of service under the new management and offer recommendations to the Board. Primary items of concern include maintaining the IASC identity, new membership recruitment, attention to international members, and general communications to members.

"Working groups are an excellent way for companies to make sure their voices are being heard by the association," said Executive Director Devon Powell. "IASC encourages all companies to consider becoming involved in these important activities that directly affect members through the governing and management of their association."

To join a working group or learn more about the mandates of the groups, contact Devon Powell at dpowell@iasc.org or 301-588-2420.



The International Aloe Science Council

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