RECOMMENDED STRATEGIES TO ADDRESS ECONOMIC ADULTERATION OF HONEY

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I. Introduction

Report

This report is generated as a core deliverable in a Marketing Service Agreement between myself (Michael T. Roberts) and the National Honey Board, styled as *Consultation for Honey Economic Adulteration Project*. Early on in this project it became evident that there are a variety of views about the nature and problem of honey economic adulteration (food fraud) and about how to resolve the problem. My aim in writing this report is to call it like I see it based on my experience as a practical problem-solver in the food space on fraud, as well as an academic with a broad perspective on the complexities involved in food fraud.

Economically Adulteration of Honey: Historical Perspective

Food fraud is both an old and modern problem. A major form of food fraud – referred to in modern terminology as Economically Motivated Adulteration (EMA) – incudes the padding, diluting, and substituting of food product for the purpose of economic gain that may or may not affect the safety of the product.

Honey has long been the subject of EMA, as evidenced in the English translation of a very old (4th or early 5th century) Roman cookbook:

> Spoiled Honey Made Good
> Ut Mel Malum Bonum Facias
>
> How bad honey may be turned into a saleable article is to mix one part of the spoiled honey with two parts of good honey.[1]

The point is that in dealing with honey adulteration or fraud we are dealing with human nature, commerce, and greed and it is interesting how on this point little has changed over history.

[1] Apicius, Cooking and Dining in Imperial Rome, Book I, p. 51 (English Translation, Dover Publications, Inc.).

Contemporary Problem

In the modern food system, trade flows of varieties of food products and ingredients from multiple locations around the world increase the level of EMA. Most researchers contend that honey is included among the foods most often subject to EMA. In this report I do not validate or question this general point that honey EMA in the United States is a problem. Instead, I assume that the audience for this report is already well versed on the honey EMA problem and that my time is much better spent on thinking about and recommending strategies in dealing with the problem.

General Observation

As noted in previous conversations, I led the California pomegranate industry's efforts to address fraud in single-source pomegranate juice, where blended and concentrated juice imported from Eastern Europe was being marked in the United States as 100% Pomegranate Juice. This illegal practice depressed the price of pomegranate juice in the United States, harming pomegranate farmers and processors in California. Even though we enjoyed success in confronting this problem, I have developed a healthy dose of cynicism about the prospects of cleaning up fraud for any particular food product line. The dynamic for cleaning up EMA pomegranate juice was unique, enabling us to implement a winning strategy. The problem of most EMA food in my view has become singularly intractable: the failure of the FDA to prioritize EMA because it does not raise food safety concerns, the challenges in coming up with effective testing of EMA, the lack of traceability in global food supply lines, and the commercial incentives to cheat all point to a lost cause. However, it has occurred to me in working on this project that there is reason to be hopeful regarding honey: there is a developing break-through in the technology on testing honey for authenticity, there is a growing recognition globally of the problem of EMA honey, and there seems to be an emerging convergence of interest in resolving the problem by researchers, scientists, industry, and governments.

Notwithstanding this optimism, I do note, however, a word of caution: a fragmented honey industry in the United States will severely limit how much can be done about honey EMA, especially given the fact that honey is a relatively small contributor – revenue wise – to the overall food economy. In my many meetings with officials and experts over the years regarding food fraud, the importance of a unified industry, especially for specialty products, has been underscored numerous times. A unified front amongst the major industry stakeholders sends a clear message to government agencies in the North America and in the EU and Asia that eradicating EMA honey is and should be a priority.

II. Assignment

Exhibit A to the Marketing Services Agreement divided my consulting services into two parts: (1) to investigate the nature and scope of honey EMA and (2) report on the investigation and provide recommendations for dealing with honey EMA.

Investigation

The assignment to investigate honey EMA involved the following components:

- Review of data, science, and legal materials relevant to the problem of honey EMA
- Interview industry representatives, key stakeholders in the honey supply chain, and experts in the field
- Assess available and emerging technologies to detect and test for honey adulteration
- Compare testing and efforts to combat EMA by other organizations for different food products
- Explore viable legal and policy tools

Report

The assignment to report on the investigation of honey involved two reports: a written report and an oral report. I also delivered an oral status report at the Honey Integrity Task Force meeting in Salt Lake City on May 19th). The written report and final oral report are to incorporate the following:

- Findings of fact that pertain to the components of the investigation

- Practical strategies – short and long-term – for testing, regulatory and enforcement efforts, and industry steps to address the problem of honey EMA

- Resources, including research, experts, and literature that would be helpful to the Honey Integrity Task Force in understanding the scope and nature of honey EMA and in adopting the strategies recommended in this report.

III. Accounting of Activities

Per the assignment outlined above, I have taken steps and engaged in certain activities in order to investigate EMA honey and draft a report of findings of fact and strategies for the eradication of EMA honey. The persons interviewed for this report are listed in Addendum A. The written resources relied on in this report for background, context, and the findings and strategies are organized and listed in Addendum B.

In addition to these interviews and readings, I also have drawn from my own experiences in dealing with EMA in food. This experience has spawned for me additional interest in economic adulteration and food fraud in general and has led to my publishing as an academic a law review article, a white paper, and a chapter in a law treatise on EMA. I have also given presentations on EMA in China, Italy, Spain, San Francisco, Washington DC, and New York City and have counseled with government officials ranging from the China FDA on food fraud in general to a government criminal task force in Italy specifically on olive oil fraud.

I mention these experiences because they have provided me with a unique international perspective on EMA that I have drawn from liberally in evaluating the information derived from the interviews and readings on the problem of honey fraud. It has been interesting to see the commonalities that exist between food product lines infected by EMA.

IV. Definition of EMA

At the Task Force meeting in Salt Lake City in May, there ensued considerable discussion about the meaning of EMA. This section briefly defines the term. Defining EMA for food products that are not meat, poultry, and certain eggs (regulated by the USDA) – such as honey – is the responsibility of the FDA (the USDA defines EMA in similar terms). Prior to 2009, the FDA had not defined EMA formally by rule or informally by guidance. A food scandal in 2007-08 involving melamine being added to pet food and infant formula in China created a global media storm that coupled food integrity with food safety, prompting the FDA to hold a public meeting on EMA and to form a working group that as part of its responsibilities, defined the term "EMA."

The working group defined EMA as the

> fraudulent, intentional substitution or addition of a substance in a product for the purpose of increasing the apparent value of the

> product or reducing the cost of its production, i.e., for economic gain. EMA includes dilution of products with increased quantities of an already present substance (e.g., increasing inactive ingredients of a drug with a resulting reduction in strength of the finished product, or watering down of juice) to the extent that such dilution poses a known or relative health risk to consumers, as well as the addition or substitution of substances in order to mask dilution

This working group definition remains the first and last definition of EMA issued by the FDA.

The EMA Working Group's definition of EMA derives from the definition of "adulteration" in the 1938 Food, Drug, and Cosmetic Act (FDCA). Section 402(b) of the FDCA lists a range of actions that constitute EMA for food products. Section 402(b) provides:

> (b) absence, substitution, or addition of constituents
>
> (1) if any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

it should be noted that section 402(b) does not expressly use the descriptor "economically motivated adulteration." It is generally accepted, however, as evidenced by the EMA Working Group's definition, that Section 402(b) implicitly provides that the acts enumerated in the section—substitution, addition, omission, dilution, and concealment—are intended by the adulterators to produce economic gain.

The failure of the FDA to define EMA more than what is provided by the Working Group is significant. With an enabling statutory provision in the FDCA, it would be expected that the FDA would formulate a rule or regulation or at the very least issue a guidance document defining EMA, giving examples of EMA actions, and express a commitment to enforce. In my view, this failure by the FDA is an abrogation of its statutory duty, but no amount of logic or shaming is going to change the FDA. Over time, as EMA detection technology improves, the agency might be more prone to investigate and enforce, but for now the agency has no plans to enforce against EMA unless the adulteration poses a real food safety risk.

It is unfortunate in many ways that we refer to this type of fraud as EMA rather than simply "fraud." The nomenclature has made it easier to relegate "EMA" as a second-tier form of

adulteration, only garnering attention from regulators when a food safety incident arises. This is unfortunate and does not reflect the will of Congress as expressed in the FDCA nor the expectations of consumers, but it is the reality in which the problem of honey EMA must be addressed.

V. Recommended Strategies

This report recommends strategies that are based on my findings of fact and that are organized into three categories: testing, enforcement, and collaboration. These strategies complement each other and represent a holistic approach to addressing EMA honey. There is no single magic bullet for ridding the food system of adulterated honey: it is a complicated problem and it should be no surprise that the strategy needs to be multifaceted.

A. Testing

Recommendation No. 1: <u>Embrace and Support NMR Testing</u>

EMA can be very sophisticated and difficult to detect for all food products susceptible to EMA, not just honey. EMA is designed by nature not to be detected. Even once specific adulterants are detected, the testing that targets these specific adulterants can become obsolete when chemists working on behalf of fraudulent food producers devise new, substitute adulterants.

Testing a food product's authenticity, rather than focusing on a specific adulterant, can also be difficult to manage because the composition of food products often varies by location, production conditions and methods, and other variables. Devising a test to account for these variables requires sophisticated authentication standards, such as one developed for pomegranate juice as delineated in a publication entitled *International Multidimensional Authenticity Specification (IMAS) Algorithm for Detection of Commercial Pomegranate Juice Adulteration.* Even though IMAS was and remains even today a gold-standard test, manufacturers of juice whose interests were threatened by the test opposed the test for a variety of reasons. Overtime, the legitimacy of IMAS, however, was accepted. The FDA, based on the information I received, adopted a simpler version of IMAS to test single-strength pomegranate juice. Eventually, simply having a test like IMAS available was itself a deterrent to the cheating.

Thus, there are two keys for success for EMA testing technology: 1) the technology needs to be sophisticated enough to be effective on a global basis and withstand scrutiny by well-

meaning critics and those whose interests would be damaged; and 2) recognized by authorities and finally by industry as the gold standard in establishing authenticity.

A type of technology that holds some promise in combatting fraud is DNA testing, which can be used to help pinpoint the identity of the product. This is most useful for species substitution in meat and fish, however, and not for products like honey.

Based on an extensive review of the historical development of testing to determine the authenticity and origin of honey, I have concluded that Nuclear Magnetic Resonance (NMR) technology applied to honey is the best testing method available now in dealing with honey EMA for the same reasons I outlined above regarding the IMAS standard for pomegranate juice.

First, NMR appears to be a sufficiently sophisticated technology to deal with a global product. Unlike other methods that focus on a particular substance, NMR analyses a spectrum that includes 36 different substances and their proportions (Luellmann, 2016). This level of sophistication is certainly needed with the adulteration of honey becoming increasingly difficult to detect. The traditional way of testing - C13-IRMS, to detect syrups from C4 plants like corn or sugar cane, along with pollen and sensory analysis of honeys – to determine purity and origin of honeys – have to give way to more sophisticated testing, as recent use of other syrups made from C3 plants (mainly from rice and undetectable by C13-IRMS) for the adulteration of honey has made detection of fraud much more difficult. In addition to detecting the addition of extraneous sugars, NMR also appears to deal effectively with the other two main modes of adulteration in the past decade: the employment of ultra-filtration and resin technology and the use of vacuum technology to reduce high moisture content in immature honey. NMR also detects botanical and geographical origins (Spiteri et al., 2015).

Second, NMR is being increasingly accepted, by testing laboratories and producers in the industry (i.e., the leading company Famille Michaud Apiculteurs was the first honey packer to take up the NMR solution and to install the instrument in their laboratory). It also appears that regulatory authorities in Europe and North America are warming to NMR as the gold-standard in testing of honey EMA.

Finally, it is likely that NMR, if accepted and employed fully, will be a deterrent to cheating. The complexity of the test will make it very difficult and expensive for adulterators. Current honey prices will make it difficult for cheaters to recover the "investment" in developing fraudulent syrup. (Norberto Garcia). Hence it has been suggested that NMR will be a decisive tool to clean up the problem of honey adulteration in the international market over the next few years. (Id.). In sum, amongst the scientific methodologies designed to

detect the artificial manipulation and adulteration of honey, NMR stands out as the most sophisticated and powerful.

The effectiveness of NMR requires the buildup of an important international database, which process is currently in full development. Hence, I recommend that the US Honey Board and Task Force do everything in its power to facilitate acceptance of NMR. A statement of support from the industry in favor of NMR and a plea to for the industry to send in samples in order to build the database is critical.

No test of EMA food is perfect. The NMR test applied to EMA honey is no exception. There are two limitations to the NMR as used with honey. First, the test is complicated and requires real experts to interpret the data. Second, the data being relied upon for the test results is not released. This does not make the test invalid, but it does make it more difficult to validate the tests. Notwithstanding these problems, the NMR technology is a powerful tool and the best option available to test the authenticity and origin of honey and should eventually win over stakeholders, leaving whatever opposition that might remain on the margins.

Recommendation No. 2: <u>Complement Support of NMR by Engaging with US Pharmacopeial (USP) on Standards Development and Testing Strategy</u>

In concert with supporting NMR testing, I strongly urge the task force to engage with USP, a scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide. The organization was founded in 1820. In 1975, it merged with the National Formulary and Drug Standards Laboratory (NF). The combined organizations publish the USP-NF which is a book of public pharmacopeial standards. Monographs for dietary supplements and ingredients are in a separate section of the USP. In 2006 the USP acquired the Food Chemicals Codex (FCC). The FCC is a compendium of internationally recognized standards for the purity and identity of food ingredients. This acquisition has helped spur USP into the food standards space.

The first whole food standard developed by USP was for single-strength pomegranate juice. Our decision to work with USP was the most important decision we made in dealing with EMA. USP's reputation for scientific integrity is without peer. The FDA defers to USP on standards-building and is very well of its work on food fraud. USP does not have enforcement authority and certainly does not replace the FDA; however, the FDA is not going to adopt a honey standard, no matter the pressure from Congress or the industry. Perhaps a little background will shed light on this point.

The passage of the 1938 FDCA was intended in large part to remedy the problem of EMA, as well as the perceived problem of imitation food. The principle approach under the FDCA became the development of standards of identity. Section 401 of the FDCA gives the FDA broad authority to choose to develop these standards. The enforcement provision for violating standards of identity is section 403(g), making a food that violates section 401 as "misbranded" under the FDCA. From the enactment of the FDCA in 1938 through the 1960s, the FDA developed and enforced standards of identity for many staple foods. The result of this development effort is 300 extant standards in twenty food categories, with dairy being the largest category, reflecting the centuries-long battle for safe, authentic milk.

Notwithstanding the success of standards of identity in preserving authentic categories of food, such as milk, the development of these standards in the 1970s began to lose favor with the FDA. The emerging view that the standards were too unwieldy and time consuming to develop was punctuated by a decade-long hearing on the identity of peanut butter that commenced in 1959 and took a decade to resolve. Standards of identity also came under severe scrutiny by Vice-President Al Gore when the Clinton administration evaluated the efficiencies of the federal government. Given the administrative and political ramifications, the FDA is no longer in the business of developing standards of identity.

The discontinuance of the development of standards of identity has not stopped a few producer groups – namely, honey and olive oil – from requesting federal standards of identity for their product lines in an attempt to eradicate EMA of imported honey and olive oil products. As the honey industry well knows, the FDA denied a citizen's petition from US honey producers that requested the FDA to adopt a honey standard of identity established by the Codex Alimentarius Commission. The FDA also denied a citizen's petition by US olive oil producers to adopt an olive oil standard of identity developed by the International Olive Council (IOC).

Based on my experience with the FDA and on recent conversations with the agency, there is no chance of the agency promulgating a standard. The good news is that in June of this year (2017), the United States Department of Agriculture has issued a draft Commercial Item Description for Honey. *See* USDA, Draft Commercial Item Description for Honey, A-A-20380 (June 2017), *available at* *https://www.nhpda.org/resources/Documents/Draft%20Commercial%20Item%20Description%20for%20Honey%20061317.pdf*
While this description does not rise to the level of a FDA standard, it is a positive step in providing a standard-like benchmark for honey authenticity.

The most important move we made in the pomegranate juice EMA project was not to spend valuable time and resources on trying to convince the FDA to promulgate a standard, but

instead to engage with the USP on the making of a viable standard. It was our read at the time that the FDA eventually would defer this space to USP anyway.

In recent years, USP has produced a guidance document on Food Fraud Mitigation, convened food fraud workshops, and created a Food Fraud Database. USP was just getting into its work on food fraud when I was handling the pomegranate juice fraud matter. Our interaction led to the standard developed by USP, much to the chagrin of those opposing our efforts, which consisted of manufacturers in the United States who purchased the pomegranate concentrate for low prices from suppliers in Eastern Europe. I was impressed that USP was not deterred by criticism and simply stayed focused on the science.

USP is well aware of NMR and its capabilities. I envision that USP would be interested in exploring ways for NMR to be used in concert with other testing methods and would be instrumental in assessing how to incorporate a testing strategy – NMR or otherwise – with the FDA and the US Customs and Border Patrol (CBP).

I underscore again that USP is a non-profit organization, has a sterling reputation for its integrity and science, and is well aware of the challenges in the global food supply chain. I recommend that a meeting be convened soon as practical between the Honey National Board and USP to assess how USP might complement the board's support of NMR and in moving forward with a testing strategy that effectively removes adulterated honey from the market.

For contact information with USP, it is best to contact: Kristi Laurvick, PhD., Senior Scientific Liaison and Karen D. Everstine, PhD, MPH, Scientific Liaison, US Pharmacopeial, http://www.usp.org. I know both of these individuals and am happy to facilitate the contact.

Recommendation No. 3: <u>Coordinate and Facilitate the Use of NMR Testing with the US Customs and Border Patrol (CBP)</u>

Such a testing strategy should involve the CBP. It is likely that CBP is interested in utilizing the NMR technology to monitor the importation of honey into the United States; however, CBP may be frustrated by the challenges in acquiring data base information from the German laboratories. Hence, I recommend leveraging USP to facilitate the CBP's efforts to test and enforce against imported EMA honey.

CBP enforces FDA and USDA regulations at ports of entry. CBP is responsible for monitoring goods and materials in cargo shipments coming into the United States at all U.S. ports of entry, and is a regular part of inspection procedures carried out at every port of entry nationwide. Imported products must meet the same standards as domestic goods,

and must contain informative and truthful labeling in English. Existing U.S. trade laws, such as general requirements under the Tariff Act of 1930 (19 U.S.C. § 1304), require all imported articles to be marked with the English name of the country of origin.

Recommendation No. 4: <u>Explore Research Relationship with University</u>

This recommendation is not as high of a priority in this "testing" category as the other recommendations, but there are many benefits that could be realized by finding a well-respected university department to help now and in the future the development of science and testing in support of authentic honey. As an example, the UC Davis Olive Oil Center at the Robert Mondavi Institute has been a hub for standards-making and research on olive oil fraud in the battle against fraud on this product. This model could be replicated for honey.

The presence of a university in the US can help ensure a credible presence in science and testing strategies on honey authenticity that complements the testing expertise in Germany and Europe. An academic hub for honey research can also build leverage for testing with the industry and establish legitimacy for emerging technologies, such as NMR. The downside is that establishing research centers can be expensive, but it may be that honey and its linkage to the eco-system would be enticing to a university agriculture research program. Various research divisions at the USDA could facilitate introductions and perhaps identify funding sources.

B. Enforcement

Enforcement against EMA honey in general rests upon two predicates. First, laws and rules that apply to EMA are only as effective as the enforcement against violations of the laws and rules. Second, no matter how sophisticated and effective the testing is for fraud, testing alone will not solve the EMA problem. Food safety experts commonly note that we can't test our way to food safety. The same is true with authenticity. Evidence of this second point is at play today in the honey industry: if honey is tested positive for adulterants in one of the two German laboratories, the honey is not destroyed, but presumably ends up on the market anyway. The result is a two-tier price structure where honey that cannot pass the NMR test in offered in large quantities and lower costs.

While it is fairly easy to establish a consensus that enforcement against EMA honey is necessary to combat the problem even with effective testing in place, the more difficult questions are who will be the enforcer and what will be the enforcement? In terms of the first question, there are three options: 1) the FDA, 2) the industry (self-governance), and 3) the courts.

Recommendation No. 5: <u>Petition the FDA to Issue Strategic Import Alerts</u>

It is natural to view the FDA as the primary enforcer; however, this route is fraught with challenges. The FDA has created a catch-22 on enforcement of EMA. The agency won't establish standards, leaving itself without a measuring stick by which to ascertain fraud, let alone take action. Moreover, unless the fraud involves food safety, the agency, as noted, will likely not enforce by way of recall, detention, fines, etc. Instead, the FDA consistently views EMA as a problem that is best resolved through labeling, a toothless enforcement solution.

There is one enforcement tool that the FDA has shown a willingness to use in recent years to enforce against EMA of imported foods – the import alert. FDA's authority over imported food is derived from Section 801 of the FDCA: Section 801(a) prescribes that a food may be refused entry into the United States if it appears to be manufactured, processed, or packed under unsanitary conditions or if it is adulterated or misbranded. An import alert is an administrative remedy that allows for a specific food article to be detained without physical examination. Import alerts are guidance documents that inform FDA field personnel that the FDA has sufficient evidence about a product, producer, shipper, or importer to determine that the food article is unsuitable for import.

Examples of import alerts for adulterated food include an import alert from the 1990s that still remains in effect, issued for apple juice and apple juice concentrate that contained an undeclared sweetener that rendered the products both economically adulterated and misbranded; an alert in August 2007 that detained farm-raised catfish, bass, shrimp, dace, and eel products from China after the discovery of unapproved drug residues and food additives; import alerts in 2008 for vegetable protein and milk products tainted with melamine from China; an alert in 2009 for morel mushrooms, due both to microbial contamination and substitution of less valuable mushrooms for a portion of the morels; an import alert in 2013 for adulterated honey that listed firms and products from India, Malaysia, New Zealand, Saudi Arabia, Turkey, and Vietnam (the same import alert noted that in the mid-1990s, detentions of imported honey from Brazil, Mexico, and the Soviet Union occurred); and an import alert in 2012 against a Turkish company and Iranian company for adulterated pomegranate juice and concentrate products that contained undeclared ingredients like "black currant, apple, pear or cherry juices in place of pomegranate juice." (This last import alert is one that we petitioned the FDA to issue.)

Once the import alert is in place, the importer has to establish negative testing results from a laboratory approved by the FDA multiple times before the alert will be lifted. The Import Alert is effective because it stops the importation completely. Technology has enabled

Customs and the FDA to communicate more effectively, thus reducing port shopping as a way to beat the alert.

The Import Alerts are typically issued against a particular company or product brand. However, the regulations and FDA policy do allow in exceptional cases for an import alert to extend to a geographical area, such as a region or even a country (melamine from China).

The FDA does not consult with the seeker of the import alert when it decides to issue the administrative remedy. They simply will issue the import alert by giving general notice in the federal register. How effective an import alert or a series of import alerts would be against EMA honey and transshipment of documents regarding honey is difficult to ascertain, but if used strategically, it may be quite effective with the caveat that constant monitoring will be necessary. Following the import alert on pomegranate juice, we found shipping documents that changed the name of the company or the product in attempt to get around alert. We were very vigilant about bringing these alterations to the attention of the FDA. Eventually, the import alert had an impact, as the East European importers cleaned up their supply line for the US and sought certification from the same US laboratory that developed and administered the IMAS test.

Recommendation No. 6: <u>Conduct Vulnerability Assessment on Honey Supply Line</u>

Self-governance is generally more appealing to industry stakeholders because of the industry's aversion towards government intrusion. Self-governance can be every effective if the industry is tightly unified and on what constitutes the enforcement mechanisms. Certification schemes, such as the one developed for honey by True Source, can be effective measures and serve an important purpose, but experience shows that without an effective enforcement regime, these measures fall short of the ultimate goal in cleaning up the fraud.

It would be premature at this point to recommend specific enforcement measures to address EMA honey. Instead, this report recommends as a first step to the devising of an enforcement scheme that the National Honey Board commission the conducting of a comprehensive vulnerability assessment. It is impossible to stop EMA honey unless sufficient information exists as to where the vulnerabilities are in the supply chain. Once those vulnerabilities are identified, then countermeasures can be put in place to remove the incentives to cheat. This methods approach will help preserve unity in the honey industry by removing morality and finger-pointing from the equation and allow the industry the latitude to devise countermeasures based on a full set of information. Based on my experience, most folks who are caught up in EMA activity are folks who in any other circumstances are honest people, but who are drawn to adulteration in order to stay in business. There are some completely unscrupulous folks who cheat as a matter of course,

but these types are at the margins and generally come from cultures where economic fraud is a lifestyle. The key for most players is to make doing the right thing less costly than doing the wrong thing.

This report identifies and distinguishes between the following three expert groups that could help devise a comprehensive vulnerability assessment:

- **Risk-based enforcement –** John Spinks, PhD, Professor, Michigan State University, Food Fraud Initiative. *See* http://foodfraud.msu.edu/about/staff/spink/. I realize Dr. Spinks has presented to the National Honey Board or at least to some members of the Board. Dr. Spinks has been around for some time and has a sound understanding EMA in all of its facets, including the issues facing honey. The vulnerability-assessment approach Dr. Spinks uses is to start at the larger enterprise level and then address vulnerable EMA points in terms of a risk perspective.

- **Forensics –** Mitch Weinburg, President, International Food Authenticity Assurance Organization (IFAAO). It is also my understanding that Mr. Weinburg has presented to some members of the Board. Mr. Weinburg is fairy new to this space, but is assertive and quite capable. His approach differs from Dr. Spinks's risk-based approach in that Mr. Weinburg uses forensic methods and tools to gather data, conduct on-site inquiries, and investigate the supply chain. The end objective is that same as Dr. Spinks – to gather information so that mitigation measures can be put into place.

- **Testing Strategies –** This investigation has brought to my attention that USP is interested in broadening its portfolio on EMA foods by offering strategizing on methods that amount to a syncing of its testing strategies with a vulnerability assessment. This is new for USP and there is not really a track record that we can use by which to judge its success.

The National Honey Board may wish to vet all three strategies. I recommend that it might be prudent in the meeting with USP on testing to include a discussion on USP's capabilities to conduct a vulnerability assessment. It is my assessment that USP will be up front about its capabilities and may even recommend that it join up on such a project with either MSU or IFAAO as co-participants. The Board could then assess a specific direction it would like to take relative to MSU and/or IFAAO. Because USP is non-profit, there would not be a charge for its services, except to cover costs. There would be a fee for services from either MSU or IFAAO.

Recommendation No. 7: <u>Consider Litigation Options</u>

Enforcement by litigation is not for the faint of heart. Using litigation as an enforcement tool requires a solid commitment, well defined goals, and a well thought out strategy. It will be important up front to define a win; often, litigation can lead to the discovery of information and documents, which can constitute a victory, even if the case itself is lost. Typically, litigation relies on a "white knight" – a company or entity that is willing and has the resources to battle unscrupulous companies that sell adulterated honey. Under the right circumstances, litigation can be an effective tool, but it is one that has a lot of rough edges and is obviously expensive and consuming.

The next few paragraphs provide background analysis to help clarify the possible role of litigation in combating honey EMA. First, it is essential to note that there is no private right of action under the FDCA. The Act does not include a private right of action to sue the FDA for enforcement of the FDCA, including its EMA- related provisions. The omission of this tool in the FDCA contrasts with its inclusion in the major environmental statutes enacted between 1970 and 1980, allowing private citizens and other interested stakeholders to bring suit against alleged violators of the statutes. These citizen-suit provisions introduce accountability into the regulation, as citizens or companies are able to take on the role of law enforcement by suing polluters and the government.

To fill this gap, lawsuits by plaintiff companies in the pomegranate juice and olive oil industries have been brought with different degrees of success. Both cases referred to below were brought under the Lanham Act, which is a federal statute that allows food companies to step into the shoes of consumers and sue another company for deceptive advertising. In a fairly recent case of *Pom Wonderful v. Coca-Cola* (2014), the US Supreme Court held that POM Wonderful was not precluded from suing Coca-Cola even when Coca-Cola had followed FDA regulations. POM Wonderful alleged that even if Coca-Cola followed the FDA regulations, its use of pictorials and other indicators on the bottles were deceptive. The US Supreme Court's ruling confirms that food companies may sue competitors for under the Lanham Act for deception even if the FDA is unwilling to take enforcement action.

Pomegranate Juice – POM Wonderful – the same company referenced in the previous paragraph that sued Coca-Cola in 2014– brought legal action earlier in 2008 under the Lanham Act against a pomegranate juice competitor, Purely Juice, Inc., who was selling pomegranate juice labeled "100 pomegranate juice" that was produced from pomegranate concentrate from suppliers in Iran and other Middle Eastern countries. POM Wonderful claimed that Purely Juice, Inc. was deceiving consumers by selling adulterated

pomegranate juice. The court agreed with the test results from seven different laboratories, which concluded that Purely Juice's juice could not have been 100 percent pomegranate juice since it contained foreign sugars, colorants, and filler juices. The court found that "it was widely known in the super premium juice industry that there were serious issues of adulteration with pomegranate juice concentrate originating from outside the United States." The court determined that Purely Juice engaged in false advertising and misleading marketing and ordered Purely Juice to pay an approximate $1.5 million toward damages. This case effectively drove Purely Juice out of business.

Olive Oil – The North American Olive Oil Association (NAOOA), a trade association representing the interests of the olive oil industry, in 2013 brought false advertising claims and sought a preliminary injunction under the Lanham Act against Kangadis Food ("Kangadis"). NAOOA alleged that Kangadis had falsely and deceptively marketed a product as "100% Pure Olive Oil" when it contained Pomace, an industrially processed oil produced from olive pits, skins, and pulp. The court preliminarily enjoined Kangadis from selling as 100% Pure Olive Oil any product containing Pomace and from selling any product containing Pomace without so indicating on the label. The court reserved ruling, however, on several issues and allowed for supplemental briefing. Following the briefing, the court in April 2013 entered an order that refused to extend its previously entered injunction due to NAOOA's failure to introduce any extrinsic evidence of consumer confusion. Although it was clear that Kangadis violated federal and state standards by selling refilled oil as 100 percent Pure Olive Oil, NAOAA failed to seek direct enforcement of the standards, which are either nonbinding or unenforceable through a private action, and could not show that a reasonable consumer's understanding of olive oil aligned with the standards. A consumer could view 100 percent Olive Oil as being silent on whether it was virgin or refined. The court's decision underscores the complexities involved in EMA litigation: violation of an industry standard alone may not be sufficient to obtain preliminary injunction on a false advertisement claim in the case of economic adulteration of food: evidence may need to be shown as to how the ordinary consumer perceives the advertisement.

Another type of litigation that serves as a gap filler is collective class action, which allows consumers to sue together as a class a food company that has committed fraud. In recent years, there has been an explosion of class action litigation over food labeling. For example, both "natural" claims and inventive ingredients like "evaporated cane juice" (otherwise known by its more conventional name, "sugar") are being litigated in many states. As a result of this litigation, some food manufacturers have changed their packaging, labeling, or ingredients. the cost of the litigation forces the company, to a degree, to internalize the cost of their practices: the individual consumers may only get a few dollars, but the settlement still costs the companies, which is a disincentive for further deceptions. That disincentive, along with the threat to the food product's brand, has a market effect: other companies

might not want to get sued for the same kinds of misbehavior. The same enthusiasm for class actions over food labeling has not been extended to EMA. A lawsuit for EMA can be more complicated than a simple labeling claim for misrepresentation. In addition to finding a laboratory to verify the fraud, the plaintiffs' counsel must also deal with complicated global supply lines to determine the responsible party or parties. An ongoing case does show, perhaps, emerging interest in EMA litigation. In Kumar v. Salov North America Corp., the plaintiff sued Salov, the maker of Filippo Berio brand olive oil, claiming violations of various California consumer protection statutes, common law fraud and deceit, breach of contract, and breach of the implied covenant of good faith and fair dealing. The plaintiff alleged Salov deceptively labeled its olive oil as "imported from Italy" when the olives were not grown or pressed in Italy, and as "extra virgin" when the way the oil is bottled, transported, and stored allows it to degrade so that it may not be extra virgin by the time of sale or by the "best by" date. A federal district court in California allowed many of the putative false labeling claims against Salov to survive dismissal, suggesting, tentatively, that there may be a future for EMA litigation.

C. Collaboration

To complement the efforts involved in testing and enforcement, this report recommends collaborative activities that offers both short-term and long-term strategies against EMA honey.

Recommendation No. 8: Persuade Supermarkets to Adopt Private Standard Regimes to Ensure Honey Integrity and Protect Honey Producers

An interesting approach that might make a real difference is to form a collaborative relationship between the honey producers and global supermarkets. The basis for this relationship would be what is commonly referred to a corporate social responsibility (CSR). The notion is that supermarkets may be interested in dealing with EMA honey via CSR in order to maintain a healthy and vibrant economic base for honey producers and their bees, thereby fostering sustainability and saving the eco-system.

CSR statements as implemented by food companies and especially multinational supermarkets integrate social and environmental concerns in their business operations. In the global food system, there has in recent years been a sharp escalation in the social roles large food enterprises are expected to play. Walmart especially, following the example of European supermarket chains, has integrated sustainability concepts into its business practices, resulting in company policies that pressure the supply chain to minimize food travel miles, reduce pesticides, follow conservation practices, and adopt other environmental impacts.

The enforcement benefit that a CSR strategy can offer is the adoption by the supermarkets of private standards. The term "private standards" is frequently interchangeable with voluntary standards. These standards typically relate to food safety, environmental impact, and animal welfare. NGOs often urge food enterprises to adopt and enforce private standards to effect changes in the food supply chain. Private standards are imposed on the supply chain in the form of contract and obligate suppliers in the food chain to meet specified standards. Thus, CSR offers enforcement by supply-chain contract as opposed to regulatory enforcement.

The Board may want to consider an introduction to the Walmart-funded Sustainability Consortium, jointly operated by the University of Arkansas and Arizona State University (see https://hbr.org/2015/02/can-walmart-get-us-to-buy-sustainable-products) to pursue the development of this concept. I may be able to assist in such an introduction, as I have numerous intersections with Walmart on food policy matters (involved in the beginnings of the Walmart Sustainability Consortium when on the law faculty at the University of Arkansas; represented Walmart on food and sustainability matters when practicing law in Washington D.C.; and presently engage with Walmart on various food law projects in China).

Recommendation No. 9: <u>Coordinate with China on its emerging efforts to eradicate food fraud</u>

On May 26 of this year, our program at UCLA organized and sponsored the *China Food Fraud Regulation and Enforcement Roundtable*, in Beijing. The Roundtable was the third event funded by Wal-Mart Store, Inc. in connection with the China Food Safety Governance Initiative developed by the Resnick Program for Food Law and Policy at UCLA School of Law. The Roundtable convened selected experts and officials to examine an emerging new rule in China designed to regulate food fraud. In total, fifty-plus invite-only guests engaged in a robust discussion of the developing new rule.

It is my understanding that in 2005, China issued its first mandatory standard for honey GB18796-2005 and the standard was updated to "GB 14963-2011 Honey" in 2011. This standard is the only mandatory standard for honey in China. GB14963-2011 provides the definition of honey and also regulates the source of nectar, sensory requirements, physical and chemical indicators, contaminant limit. A product marketed as "honey" must satisfy all the requirements in this standard.

China consumers are no different than consumers in the US: they are not well informed on honey adulteration and they have strong beliefs that food should be authentic and not

adulterated – economic or otherwise. It is my impression the timing now is good for a strong pitch for honey authenticity in China. There is considerable pressure from the PRC on the China FDA and organized committees to deal with the problem of food fraud in general. China overall is moving forward in a more sophisticated and professional direction on food regulation. Driven by food security objectives, China is also increasingly becoming engaged in global food matters, as evidenced by ChemChina's recent acquisition of Syngenta (Swiss farm and chemical giant) and the purchase by another China company of Smithfield Foods (US meat processing company). It is also reported that China intends to accumulate additional agricultural resources world-wide, especially grains and soybeans. The point being that China is on the move now in addressing food safety, food security, and sustainability concerns, making the political and regulatory environment more conducive to enforcing against food fraud.

There is no shortage of expert liaisons between China and US food and agricultural interests, but there is one China firm in particular that I think is quite effective in representing US interests with the China FDA and other government officials on food issues – Food Coordinate Consulting (FCC). FCC is comprised of law professors and scientists and represents a number of different food companies and associations doing business in China. In fact, Dean Yu, who is a member of FCC and an associate Dean for a law school in Shanghai, is on the drafting committee for China that is writing the new rule on food fraud.

The contact person for FCC in China is Edison Tang, Chief Operating Officer. FCC is headquartered in the Hui District in Shanghai, but works on matters throughout China involving food issues.

Recommendation No. 10: <u>Coordinate with the EU, especially the Europol-Interpol Food Fraud Task Force</u>

In some cases, EU member countries have begun acting aggressively to combat EMA: for example, Italy has stepped up its enforcement of strict criminal and civil penalties for olive oil frauds. Europol and Interpol are now treating food fraud as a significant activity and source of revenue for transnational organized crime. Operation Opson IV, the fourth iteration of the Europol-Interpol food fraud task force, resulted in the seizure of more than eleven thousand metric tons of fraudulent goods in 2015 by utilizing the cooperation of law enforcement agencies in forty-seven countries, including the United States.

I recommend that the National Honey Board make an effort to coordinate with the EC enforcement activity. The USDA via its Foreign Agricultural Service (FAS) offices might be able to facilitate such an exchange. The advantage to enforcement in the EU is the incentive it provides for the US FDA to step up its enforcement efforts as well.

It is also important to note the announcement last week of the new China-EU effort to combat EMA food. This is a significant development and it may behoove the US honey industry to contribute where it can to these efforts.

Recommendation No. 11: <u>Devise Media Strategy</u>

Numerous news reports and articles over the last few years evidence the media's interest in EMA in general. The media in China alone has aggressively sought to publish stories on food fraud. It behooves the National Honey Board to be proactive and have in place a media strategy that reflects the objectives and values of the honey industry, especially with a focus on authenticity and the eco-system benefits of a vibrant, healthy honey market that represents safe, health, and authentic honey.

This strategy could be developed in-house or farmed out to an expert consulting firm.

Recommendation No. 12: <u>Unity!</u>

Last but not least, it is important to reiterate the point made at the start of this report – it is critical for the honey industry stakeholders to be unified in their attempt to eradicate honey EMA. The FDA, public officials, foreign governments, and the industry will all benefit if the US honey industry speaks for one voice on strategies to deal with EMA honey.