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Defining and Implementing Science: Exploring the Science-Based Standard within the Food Safety and Modernization Act

by

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I. Introduction

Thomas Jefferson wrote in a letter to his fellow founder John Jay: "Cultivators of the earth are the most valuable citizens. They are the most vigorous, the most independent, the most virtuous, and they are tied to their country and wedded to its liberty and interest by the most lasting bonds."[1] The sentiment in Jefferson's words was shared by many of the founding fathers and the legacy has affected farm policy in the United States.[2] The attitude reflects an awareness of the uniqueness and importance for agriculture within the national economy and culture. Over the last two centuries, the United States has developed a comprehensive scheme for supporting, regulating, and oversight of American farms, mostly through the Food and Drug Administration, the United State Department of Agriculture, and the Environmental Protection Agency, as well as various state agencies. In total, fifteen various federal agencies are responsible for overseeing and regulating food safety.[3] Yet despite the number of federal and state agencies monitoring the nation's food supply, over 48,000,000, or one in six, Americans get sick every year from food borne illnesses.[4] An additional 128,000 people are hospitalized and 3,000 die from food borne illnesses annually.[5] At even a cursory glance, the current methods of ensuring food safety are ineffective and, at the very least, allow mistakes to happen.

In response to the number of food borne illnesses reported annually, Congress passed the Food Safety and Modernization Act (FSMA), which was signed into law by President Obama on

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[1] *Letter from Thomas Jefferson to John Jay,* (Aug 1785), http://avalon.law.yale.edu/18th_century/let32.asp.
[2] Richard S. Kirkendall, *Up to Now: A History of American Agriculture from Jefferson to Revolution to Crisis*, AGRICULTURE AND HUMAN VALUES, Winter 1987, at 4, 4-5.
[3] Geoggrey S. Becker, *The Federal Food Safety System: A Primer*, CONGRESSIONAL RESEARCH SERVICE REPORT, Rept. No. RS22600, at 1 (April 20, 2010).
[4] Food and Drug Administration, Food Safety and Modernization Act: Frequently Asked Questions (2011), http://www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM259776.pdf.
[5] *Id.*

January 4, 2011.[6] Met with glee by consumer advocates and caution by the food industry, the FSMA, which has been considered "historic", is geared toward preventing food borne illnesses and pinpointing the source when outbreaks do occur. Previously, the Food and Drug Administration (FDA) relied on voluntary recalls and generally accepted practices to promote a safer food supply. With the passage of the FSMA, the FDA now has broader power to deal with food safety from every aspect of the production line.[7] Among other things, the FSMA directs the FDA to establish science-based standards for the safe production and harvesting of fruits and vegetables, with some minor exceptions.[8] Although the new regulations for fresh produce were supposed to be issued about two years after the FSMA went into effect, it is likely they will be further delayed.[9] In the meantime, growers are trying to anticipate what types of new regulations they will be required to follow and how this will affect the bottom line. Meanwhile, consumer advocates are impatient for stricter and more thorough protections.

The main focus of the Food Safety and Modernization Act is preventative measures to protect the food supply. To guide the FDA in creating preventative regulations for growers, the FSMA calls for "contaminant-specific and science-based guidance documents . . . or regulations" that "reduce the risk of serious illness or death to humans or animals or to prevent adulteration of the food . . . or to prevent the spread by food of communicable disease…."[10] The inclusion of a science-based standard helped secure support from leading agricultural industry groups for the

[6] Food Safety and Modernization Act, 21 U.S.C.A. §2201-2252 (West 2011).
[7] *Id.*
[8] 21 U.S.C.A. § 2201(West 2011).
[9] FOOD AND DRUG ADMINISTRATION, BACKGROUND ON THE FDA FOOD SAFETY MODERNIZATION ACT (FSMA) (2011), http://www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM263773.pdf. ("Final regulation [for fresh produce] due about 2 years following enactment").
[10] 21 U.S.C.A. § 2201(West 2011).

FSMA.[11] In order to write preventative regulations and apply them, the government agencies are relying on past procedures. Previously, the USDA and many state agricultural agencies issued Generally Accepted Practices guidance documents for safe production of food. In 2009, the FDA issued new guidance documents for melons, leafy greens, and tomatoes, as well as a guide to preventing microbial organisms for fresh fruits and vegetables. Though the guidance documents were issued as guidelines in the past without any statutory requirement for scientific backing, the FDA has suggested they will probably be used as a starting point for the new regulations under the FSMA.[12] However, the question remains how a science-based standard will be satisfied and, if it is, how effective it will be to ensure quality preventative measures, while at the same time protecting the agricultural industry from supposedly arbitrary regulations.[13]

Despite the clear requirement of a science-based standard, it is not necessarily obvious what such a legal standard would look like in the context of agriculture. In general, science is riddled with debate, but courts cannot wait until the scientific community reaches a consensus, or even a majority, before deciding a case. Therefore, there should be an administrative test or guideline established which may determine whether a rule is sufficiently supported to meet a science-based standard if one is required, such as under the FSMA. Once such a test is developed, it is important to consider whether the 2009 guidance documents issued by the FDA would meet the requirements and be considered science-based. First, we will consider what the

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[11] *See* ISSUE STATEMENT ON FOOD SAFETY AND LABELING, AMERICAN FARM BUREAU FEDERATION (Jan 2012) , http://www.fb.org/issues/docs/foodsafety12.pdf.

[12] FOOD AND DRUG ADMINISTRATION, FOOD SAFETY AND MODERNIZATION ACT: FREQUENTLY ASKED QUESTIONS (2011), http://www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM259776.pdf.

[13] The agriculture industry relies on the so-called science-based standards in various contexts to prevent supposedly arbitrary rules and regulations. For other examples, see Charles Bronson, *Florida already has a science-based plan on pollutants*, TAMPA BAY TIMES, Nov. 9, 2009 and Helena Bottemiller, Industry Commends USDA for Codex Support, FOOD SAFETY NEWS, Sep. 1, 2011, *available at* http://www.foodsafetynews.com/2011/09/food-and-ag-industry-commends-usda-for-codex-support/ (quoting the FICC's letter to Secretary of Agriculture Vilsack, thanking him for continued support of science-based standards for Codex issues) .

scientific community considers legitimate science, including how much scientific evidence is necessary to support regulation. Next, an examination of the evidentiary standards for science, as determined by the United States Supreme Court, will be considered. Finally, we will consider the basis for the 2009 guidance documents and determine whether they could meet the science-based standard of the FSMA. The 2009 guidance documents probably could meet a scientific-based standard under the FSMA, but only because the recommendations are broad and generalized. However, the science-based standard does not live up to the expectations of the agriculture industry and does not necessarily provide practical guidance for implementing food safety measures.

II. What is Science?

So long as human beings have been curious about the natural world around them science has existed in some form or another. The definition of science, however, can be somewhat elusive and clearly changes with time. So-called sciences that were once accepted, such as astrology, are no longer considered credible. So, what is science? According to Webster's Dictionary, science is "knowledge or a system of knowledge covering general truths or the operation of general laws especially as obtained and tested through scientific method."[14] However, this broad definition does little to explain what science is, let alone how an administrative agency may apply such a standard. In order to implement a science-based standard, such as the one found in the Food Safety and Modernization Act (FSMA), it is necessary to understand what actually counts as science.

To create a framework for a scientific standard to apply for administrative rule promulgation, consideration of what scientists consider legitimate, credible science is a good

[14] MERRIAM-WEBSTER DICTIONARY (2012).

starting point. Essentially, science is a puzzle that must be solved. Research and study are the means of gathering the pieces and then putting them together. Scientific research is "the scientific investigation of phenomena which includes collection, presentation, analysis and interpretation of facts that links an individual's speculation with reality."[15] "Normal-scientific research is directed to the articulation of those phenomena and theories that the" prevailing body of science has supplied, in order to more fully understand them.[16] The actual means used to study science, however, are extremely important. They are established, generally accepted methodologies of study, which include a hypothesis, analysis, known error rates, and replication.[17] When these important tools are utilized, they allow scientists to understand and develop more thoroughly the area of science being researched. The level and depth of understanding for any given scientific hypothesis is constantly increasing as the research is completed.

Inherently then, science does have a level of uncertainty, debate, and dissent. None of those, however, necessarily means that the current approach is incorrect or wrong. In fact, a bit of uncertainty is preferred, to an extent, in science so that theories can be strengthened and more precise research can be done. In fact, "[e]specially in the early stages, questioning and dissident opinion are hugely useful. It is most important that the consensus is not reached too early, too glibly, because it can inhibit fruitful lines of investigation."[18] At a certain point though, complete certainty is not necessary for science to accept theories and implement them for the benefit of

[15] *See e.g.*, ResearchMethods.org, Meaning and Characteristics of Research, (October 11, 2011) http://www.researchmethod.org/meaning-and-characteristics-of-research/ (last visited April 20, 2012).
[16] THOMAS S. KUHN, THE STRUCTURE OF SCIENTIFIC REVOLUTIONS 25 (3rd ed. 1996).
[17] ResearchMethods.org, Meaning and Characteristics of Research, (October 11, 2011) http://www.researchmethod.org/meaning-and-characteristics-of-research/ (last visited April 20, 2012).
[18] Howard Silverman, *Lord May: Science as Organised Scepticism*, PEOPLE AND PLACE (April 27, 2010), *available at* http://www.peopleandplace.net/on_the_wire/2010/4/27/lord_may_science_as_organised_scepticism.

society. This is especially true in regulations meant to prevent future harms, such as the goals of the FSMA. In the cases of this type of science:

> [W]ith the aims of occupational, and almost synonymously preventive, medicine in mind the decisive question is whether the frequency of the undesirable event B will be influenced by a change in the environmental feature A. How such a change exerts that influence may call for a great deal of research. However, before deducing 'causation' and taking action we shall not invariably have to sit around awaiting the results of that research. The whole chain may have to be unraveled or a few links may suffice. It will depend upon circumstances.[19]

Therefore, it is not always possible, due to incomplete information, for science to be able to completely and fully explain how or why there is an association between cause and effect. However, those connections may be made so long as research is able to show a sufficient enough correlation between two events to establish causation. Examples of such circumstances include the link between cigarette smoking and lung cancer, or more historically, the relationship between chimney sweeps and certain kinds of illness.[20] In both of these instances, it is not necessary for scientists to be able to pinpoint exactly what the connection is; rather, it is more important the pertinent information be released in order to prevent further harm.[21] As a result of the research between smoking and lung cancer, regulations and rules were put into place reflecting the association. Thus, science does not have to explicitly explain the details of a causal connection, especially when it is used for preventative measures. Recognizing then that science does not always have a complete understanding, it is still possible to use meaningful, though incomplete, research to implement rules and regulations based on the information known. As new studies are completed, the practices of preventative measures can be updated and refined to reflect the new research.

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[19] Sir Austin Bradford Hill, *Then Environment and Disease: Association or Causation?*, PROCEEDINGS OF THE ROYAL SOCIETY OF MEDICINE, (Jan 14, 1965).
[20] *Id.*
[21] *Id.*

Science is never static; it is always changing and evolving as research is conducted, which unveils new information. Through the scientific process, better understanding of scientific theories is gained through experiments, studies, and research.[22] Within the attempts at gaining a better understanding, there are some aspects of scientific research and discovery that are inherent to normal science.[23] If a branch of science is going to be considered legitimate and credible, it is essential that it follows certain, accepted practices.[24] While these methodologies do not eliminate the reality that scientific evidence may be incomplete, they do ensure that the information acquired through the discovery process is credible and reliable. Without such accepted practices, it would be impossible for the legal system to regard any type of science as dependable enough to meet a science-based standard. The United States Supreme Court has approached this very issue in *Daubert v. Merrell Dow Pharmaceuticals*, where the Supreme Court listed various methods that can be deemed scientifically credible.[25] *Daubert* was later codified in the Rules of Evidence as Rule 702, which simplified the test.[26] There are also other contexts in which the Supreme Court has approached the issues of whether various areas of so-called science were supported by any credible scientific methods, such as discussing whether creationism or intelligent design may qualify as science.[27] In other contexts, the courts have relied on standards established by the *Daubert* case, even if not mentioned by name.

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[22] THOMAS S. KUHN, THE STRUCTURE OF SCIENTIFIC REVOLUTIONS 25 (3rd ed. 1996).
[23] *Id.* at 10-11.
[24] *Id.* at 25.
[25] Daubert v. Merrell Dow Pharm. Inc., 509 U.S. 579 (1993).
[26] Fed. R. Evid. 702.
[27] *See* Kitzmiller v. Dover Area Sch. Dist., 400 F. Supp. 2d 707 (M.D. Pa. 2005) and Edwards v. Aguillard, 482 U.S. 578 (1987). The Supreme Court and lower courts have rejected both creationism and intelligent design as scientific theories because they lack the methodology used in normal science. The *Kitzmiller* court found intelligent design was not science because "(1) ID violates the centuries-old ground rules of science by invoking and permitting supernatural causation; (2) the argument of irreducible complexity, central to ID, employs the same flawed and illogical contrived dualism that doomed creation science in the 1980's; and (3) ID's negative attacks on evolution have been refuted by the scientific community."

While *Daubert* has been codified into a Rule of Evidence, the case is still relevant in that it explains the types of evidence which will qualify as credible and legitimate science. The *Daubert* case was brought by two infants born with birth defects, allegedly because their mothers had been given a drug called Bendectin during the first trimester of their pregnancies.[28] Merrell Dow, the pharmaceutical company, denied there was any causation between the drugs and the birth defects.[29] The biggest issue in the case emerged when the parties sought to introduce expert testimony to support their claims. Merrell presented experts whose testimony was based on studies of the drug's side effects on human beings.[30] On the other hand, the infants' expert witnesses had based their testimony on animal studies and translated the results to apply to human beings for litigation.[31] The trial court held the infants' witnesses were insufficient because the testimony was not based on human studies and could not raise an inference of causation.[32] The issue of whether the experts' testimony was admissible based on its scientific qualifications was appealed all the way to the Supreme Court of the United States. While *Daubert* was not about science-based regulations enforced by an executive agency, as in the FSMA, the *Daubert* holding and subsequent test gives insight into what the Supreme Court considers reliable methods of science. In fact, the case has become a hallmark for qualifying the scientific testimony of expert witnesses. Therefore, a review of the test and factors set forth by the Supreme Court, could be helpful in determining what types of scientific evidence an administrative agency may rely on to promulgate rules requiring a scientific basis.

The Supreme Court's holding in *Daubert* is not necessarily radical, but it did change existing precedent. Previously, expert witnesses could proffer testimony if it was "generally

[28] *Daubert*, 509 U.S. at 582.
[29] *Id.*
[30] *Id.*
[31] *Id.* at 583.
[32] *Id.* at 583.

accepted" in the scientific community.[33] The Supreme Court replaced the previous standard and held:

> ….[T]he trial judge must determine at the outset, pursuant to Rule 104(a), whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and whether that reasoning or methodology properly can be applied to the facts in issue.[34]

The Court then set out a list of factors the trial judge should consider when determining whether evidence proffered by an expert witness was credible. First, a judge should be sure the scientific knowledge has been tested based on the traditional methodology of hypotheses and testing.[35] Next, the judge should consider whether the evidence has been peer reviewed and published.[36] Here, however, the Supreme Court cautions that "well-grounded but innovative theories will not have been published" and "[s]ome propositions, moreover, are too particular, too new, or of too limited interest to be published."[37] Therefore, peer review and publication may be seen more as just a factor of credibility, rather than a necessary element. Third, the Supreme Court suggests a judge should keep in mind the rate of error of any given scientific testing.[38] In addition, the judge should inquire as to whether there is acceptance within the scientific community of the evidence being proffered.[39] Finally, the scientific knowledge should be relied on by other experts in the field, not just the expert witness in litigation.[40] Despite these factors, however, the Court

[33] *Daubert*, 509 U.S. at 586.
[34] *Id.* at 592-593.
[35] *Id.* at 593.
[36] *Id.*
[37] *Id.*
[38] *Daubert*, 509 U.S. at 593.
[39] *Id.* at 594.
[40] *Id.* at 595.

advises that "the focus, of course, must be solely on the principles and methodology, not on the conclusions they generate."[41]

The Supreme Court also discussed public policy issues related to the new analysis for expert witnesses based on scientific knowledge in *Daubert*. On the one hand, there was a concern that this new standard would allow a free for all of ridiculous scientific studies which would confuse the jury. The Court responded that the traditional protections of a fair trial would suffice to ensure the integrity of the proceedings, including "vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof…."[42] Further, the court may use summary disposition or a directed verdict when the judge deems it appropriate.[43] On the other hand, there was a concern that the standards set forth in the opinion require the court to only rely on a sort of scientific orthodoxy, which does not allow for new and fresh scientific theories to be considered in the courtroom. However, the Supreme Court merely suggests that a balance must be struck between final and binding judgments, and excluding evidence that may actually be credible without meeting the standard.[44] Therefore, the Supreme Court acknowledged that some scientific evidence that does have merit will be excluded during litigation that could change the outcome of a case.

Since the time of *Daubert*, Rule 702 of the Federal Rules of Evidence has been rewritten to more accurately reflect the changes wrought by *Daubert* and its progeny. The rule now states:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or

[41] *Id.*
[42] *Id.* at 596.
[43] *Id.*
[44] *Id.* at 597.

> data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.[45]

The requirements of (a), (b), and (d) relate to relevancy to the case. Most importantly though, (c) relies on the phrase "reliable principles and methods" to express the test set forth in *Daubert*. While the new language of the rule obviously does not explicitly list the factors set out by the Supreme Court in *Daubert*, the language does suggest that the factors are flexible and not all are required. Therefore, a court's determination of whether expert testimony is based on credible scientific knowledge will still require an analysis of the *Daubert* factors and its progeny.[46]

Rule 702 and *Daubert* may give a framework for judicial determination of a scientific standard, even outside the context of expert witnesses. While science operates with some level of uncertainty, there are also specific indicators of reliability. Many of these indicators were used in the *Daubert* opinion to determine the sufficiency of expert witnesses. Therefore, when considering whether the science used to support a regulation has sufficient credible support, the *Daubert* factors could be applied to determine credibility of the underlying science. The factors are: 1) whether the data has been tested using generally accepted scientific methods, 2) whether the research has been peer reviewed and published, 3) the error rate of any research relied upon, 4) whether there is acceptance in the scientific community, and 5) whether the information is relied on by experts in the field, not just used for litigation purposes.[47] If the factors are mostly met, then a regulation can be considered science-based, even with some level of incomplete scientific knowledge. Further, the public policy concerns regarding the *Daubert* factors may be

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[45] Fed. R. Evid. 702.

[46] *See also* Huber v. JLG Industries, 344 F. Supp. 2d 769, (D.Mass. 2003) ("It is true that many cases rely on the *Daubert* factors as evidence of the three new criteria in Rule 702 but the *Daubert* factors are not talismanic."), Milward v. Acuity Specialty Products Group, 639 F.3d 11 (1st Cir. 2011) (indicating the proponent of evidence must only prove scientifically reliable methods were used), Gen. Elec. Co. v. Joiner, 522 U.S. 136 (1997) (indicating the judge must ensure evidence is reliable and relevant).

[47] *See Daubert*, 509 U.S. at 509-601.

addressed through the various stages of promulgating rules, such as the comments period. Since there is a science-based requirement under the FSMA for regulation of fresh produce, the *Daubert* factors could be used as a guideline by the FDA when promulgating any of the rules.

III. Food Safety and Modernization Act

The Food Safety and Modernization Act (FSMA) requires the Food and Drug Administration (FDA) to "issue contaminant-specific and science-based guidance documents . . . or regulations…" in order "to reduce the risk of serious illness or death to humans or animals . . . "or to prevent the spread by food of communicable disease …."[48] While the rules have not yet been promulgated, many have speculated and the FDA has suggested that the 2009 Generally Accepted Practices guidance documents for leafy greens, tomatoes, and melons is a strong indication of how the agency will draft the eventual rules.[49] The guidance documents describe various known health risks posed by growing, harvesting, and packaging the fresh produce. Published in 2009, however, the guidance documents were produced prior to the passage of the FSMA. Therefore, the FDA did not necessarily consider the science-based standard created by the statute when drafting the documents. Rather, the agency relied on standard administrative procedures. The question then, is whether the guidance documents are able to meet the science-based statutory requirements of the FSMA. Reviewing the recommendations and applying the *Daubert* standard to the scientific support of the guidance documents may determine if they could be officially adopted under the statute. The following section will review relevant portions

[48] 21 U.S.C.A. § 2201(West 2011).
[49] FOOD AND DRUG ADMINISTRATION, FOOD SAFETY AND MODERNIZATION ACT: FREQUENTLY ASKED QUESTIONS at 24 (2011), http://www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM259776.pdf (indicating producers may start assessing food safety issues on their farms and using the guidance documents as guidelines). *See* FOOD AND DRUG ADMINISTRATION, GUIDANCE FOR INDUSTRY: GUIDE TO MINIMIZE MICROBIAL FOOD SAFETY HAZARDS OF MELONS; DRAFT GUIDANCE (2009); FOOD AND DRUG ADMINISTRATION, GUIDANCE FOR INDUSTRY: GUIDE TO MINIMIZE MICROBIAL FOOD SAFETY HAZARDS OF TOMATOES; DRAFT GUIDANCE (2009); FOOD AND DRUG ADMINISTRATION, GUIDANCE FOR INDUSTRY: GUIDE TO MINIMIZE MICROBIAL FOOD SAFETY HAZARDS OF LEAFY GREENS; DRAFT GUIDANCE (2009).

of the guidance document's recommendations for melons. Finally, consideration will be given to what a science-based standard actually means practically, for the farmers and packagers trying to implement the rules or recommendations.

While FDA was not under any special science-based requirement when the agency created the guidance documents, there was still an administrative standard to follow. In addition to following directives of a statute, executive agencies must promulgate rules in accordance with the Administrative Procedures Act (APA). The APA requires an executive agency to create rules that are not deemed arbitrary or capricious, among other requirements.[50] Further, the rules must be supported by substantial evidence.[51] As a result, when an agency does promulgate rules they must be based on and supported by something that can be considered reasonable. Under the requirements of the FSMA, the rules for fresh product must be science-based.[52] Therefore, in order for the rules to meet the requirement for substantial evidence, they must be supported by science. The *Daubert* standard is a floor for determining whether science is credible. While the *Daubert* standard is meant for the adversarial context of a trial, the factors can be easily translated to an administrative setting. If the factors of *Daubert* are used to evaluate the credibility of the FDA's support for the guidance documents, there may be a clear indication of whether the science-based requirement of the FSMA is met. Applying the standard to the guidance documents then will provide a way for support to be tested.

The guidance documents released for melons, entitled Guide to Minimize Microbial Food Safety Hazards of Melons, offers suggestions for minimizing food borne illnesses associated

[50] Administrative Procedures Act, 5 U.S.C.A. § 706 (West).
[51] *Id.*
[52] 21 U.S.C.A. § 2201(West 2011).

with melons.[53] The document is broken into several parts pertaining to the various aspects of melon production from the field to the table. These sections include production and harvest, postharvest, fresh-cut and value added processing, distribution, and user handling for retail and food services.[54] Each section contains an overview of the associated risks and problems, followed by recommendations for minimizing those associated risks to melons. In addition, the FDA has included a section for the references used as support to create the suggestions.[55] Presumably, these references would be, at least part of, the scientific basis for the guidance documents. A consideration of the individual directives and the supporting research should provide insight as to the scientific basis for some of the recommendations, and also give an idea of what the FDA will require when the actual rules for the FSMA are promulgated.

Production is the first section of the melon guidance document and includes rules related to climate and characteristics of the melon rind. For climate conditions, since melons are grown best in warm, humid conditions, the FDA warns producers against the increased appearance of wildlife "in the production environment [which] are known to be potential carriers of human pathogens."[56] Based on this caution, several suggested practices are listed to prevent the dangers, including "[m]onitoring and reducing, to the extent possible, domestic animal, wildlife, and insect activity in melon production environments," "[e]valuating whether to harvest portions of melon fields when there is evidence of unusually heavy wildlife pest infestations," and "[d]elaying harvest and performing extra washing when heavy rains have recently occurred."[57] Further, farmers are recommended to conduct "environmental assessments on the topography,

[53] FOOD AND DRUG ADMINISTRATION, GUIDANCE FOR INDUSTRY: GUIDE TO MINIMIZE MICROBIAL FOOD SAFETY HAZARDS OF MELONS; DRAFT GUIDANCE (2009) http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm174171.htm#ref.
[54] *Id.*
[55] *Id.*
[56] *Id.*
[57] *Id.*

land history, risk of flooding, adjacent land use, and domestic animal and wildlife presence associated with the production environment, using concepts that are outlined in the GAPs Guide."[58]

In order to support the recommendations given in the climate and environmental conditions section, the guidance document cites two sources. The first article is entitled *Climate Change and Extreme Weather Events; Implications for Food Production, Plant Diseases, and Pests* and was published in Global Change and Human Health.[59] The second article, entitled *The Novel and Endemic Pathogen Hypotheses: Competing Explanations for the Origin of Emerging Infectious Diseases of Wildlife*, explores the way pathogens spread in two varying hypotheses.[60] It was published in *Conservation Biology*, a peer reviewed journal, and has been cited by 12 different articles in various scholarly journals. Applying the *Daubert* factors to the latter article, it obviously meets three of the factors automatically: it was published in the peer reviewed journal *Conservation Biology*, it has been accepted in the scientific community, and it is relied on within the field. Since the *Daubert* factors are to be considered overall and not as elements, it is likely the FDA could find the first source to be scientifically-based. Therefore, these recommendations could be considered science-based and potentially promulgated under the FSMA by the FDA.

Although the guidance documents list only two articles to give scientific support to the dangers of wildlife carrying human pathogens, much more research obviously exists to support that conclusion. It has long been recognized and acknowledged that rats and fleas were the main

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[58] *Id.*
[59] *Id.*
[60] J. Rachowicz, et al., *The Novel and Endemic Pathogen Hypotheses: Competing Explanations for the Origin of Emerging Infectious Diseases of Wildlife,* CONSERVATION BIOLOGY, 2005, at 1441–1448.

source for the frequent outbreaks of bubonic plague in the Middle Ages.[61] The fleas and rats, once infected by the plague, were able to transmit the disease to humans.[62] Since that time, many studies and numerous research has been conducted that link wildlife and pathogens.[63] Insects and animals can be associated with the spread of many pathogens, including *E. coli* and *Salmonella*.[64] Recently, the spread of the West Nile Virus has been linked to mosquitoes, which transmitted the virus to other animals and directly to humans.[65] The amount of scientific evidence linking wildlife and insects to the spread of human pathogens is vast. It is also generally accepted in the scientific community as a source for health risks. Therefore, although the FDA only gave citations to two studies supporting the proposition that wildlife can be a source of disease, the science is overwhelming. Clearly, support could be easily found to meet the credibility factors of *Daubert*. Under the FSMA's science-based requirement for rules regulating fresh produce, it would be very easy for the FDA to support any of these recommendations or rules with scientific data.

Despite the abundance of scientific research and data, the FDA's recommendations for melons are left wanting for specifics and clarification. The actions suggested by the guidance document are extremely general in the application of preventing health concerns. The generalities almost make the science-based requirement of the FSMA moot, because any of the

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[61] *See e.g.*, Boris Velimirovic & Helga Velimirovic, *Plague in Vienna*, REVIEWS OF INFECTIOUS DISEASES VOL. 11, NO. 5 (1989).
[62] *Id.*
[63] *See e.g.*, A. Dobson & J. Foufopoulos, *Emerging Infectious Pathogens of Wildlife*, PHILOSOPHICAL TRANSACTIONS: BIOLOGICAL SCIENCES VOL. 356, NO. 1411 at 1001-1012 (2001); Morton N. Swartz, *Human Diseases Caused by Foodborne Pathogens of Animal Origin*, CLINICAL INFECTIOUS DISEASES VOL. 34, SUPPLEMENT 3 at S111-S122 (2002); Meena Ramchandani, Amee R. Manges, Chitrita DebRoy, Sherry P. Smith, James R. Johnson & Lee W. Riley, *Possible Animal Origin of Human-Associated, Multidrug-Resistant, Uropathogenic Escherichia coli*, CLINICAL INFECTIOUS DISEASES VOL. 40, NO. 2 at 251-257 (2005).
[64] Morton N. Swartz, *Human Diseases Caused by Foodborne Pathogens of Animal Origin*, CLINICAL INFECTIOUS DISEASES VOL. 34, SUPPLEMENT 3 at S111-S122 (2002).
[65] *See e.g.*, Peter P. Marra, Sean Griffing, Carolee Caffrey, A. Marm Kilpatrick, Robert McLean, Christopher Brand, Emi Saito, Alan P. Dupuis, Laura Kramer & Robert Novak, *West Nile Virus and Wildlife,* BIOSCIENCE VOL. 54, NO. 5 at 393-402 (2004).

recommendations can easily be proved to reduce the spread of human pathogens with scientific research. For example, the FDA suggests farmers "[t]rain[] harvest employees to recognize and report signs and evidence of wildlife pest infestations (e.g., feces) and take appropriate actions."[66] It would be difficult to argue against the statement that the presence of wildlife around harvest increases the risk for spreading human pathogens. Given the abundance of research and data supporting the premise, despite not being explicitly listed in the guidance documents, the recommendation is easily supported. Therefore, the FDA could promulgate the rule under the FSMA and comply with the science-based requirement. The general character of the suggestion grants the FDA the ability to point to a large body of science to support it, but in reality, the recommendation gives little guidance to farmers. In this example, employees are supposed to take so-called "appropriate actions."[67] Nowhere in the guidance document is "appropriate actions" defined, explained, or clarified. For the farmer attempting to comply with the recommendation, it would be difficult to know exactly how the FDA expects the situation to be handled so the farm is in compliance. Further, the generality of the recommendation may result in variation of application by growers. Ultimately then, the goals of preventing food borne illnesses may be thwarted by unsatisfactory compliance. Therefore, while the recommendation is science-based and complies with the requirements of the FSMA, it is hopelessly too general to give actual direction.

A glimpse of the other recommendations in the section reveals they are also general enough to be supported by mounds of scientific research and data, but not specific enough to practically provide guidance. The first recommendation asks farmers to "[c]onduct[]

[66] FOOD AND DRUG ADMINISTRATION, GUIDANCE FOR INDUSTRY: GUIDE TO MINIMIZE MICROBIAL FOOD SAFETY HAZARDS OF MELONS; DRAFT GUIDANCE (2009).
[67] *Id.*

environmental assessments on the topography, land history, risk of flooding, adjacent land use, and domestic animal and wildlife presence associated with the production environment….”[68] Certainly an assessment of those factors could contribute to the likelihood of animals being present and an increased risk for human pathogens. However, no guidance is given to what a farmer should consider when doing an assessment, what types of risks are present, or what level of risk should be avoided. Likewise, the next recommendation advises farmers to “[m]onitor[] and reduc[e][], to the extent possible, domestic animal, wildlife, and insect activity in melon production environments….”[69] Again, many questions remain as to how this guidance could actually be complied with by farmers. Is certain paperwork necessary? Is there a certain amount of wildlife and insect activity that is acceptable or a level where it is no longer acceptable? Although scientific research is available which would almost certainly allow the recommendations to be promulgated as rules under the FSMA, the guidance documents are too general to be of much use.

The guidance document also includes recommendations, included in the section regarding postharvest care, for farmers when handling freshly harvested melons. The overview for top icing explains the risks associated with using ice during transportation. During transportation, the ice is not kept at freezing temperatures. As a result, “[m]elting ice water flowing through boxes of melons may increase the risk of melon cross-contamination within and among pallets of melons.”[70] In order to avoid contamination of the melons as a result of this melting ice, the FDA lists recommendations. The suggestions include: “[e]nsuring that the water used to make ice is of sufficient microbial quality for its intended use,” “using ice that contains a

[68] *Id.*
[69] *Id.*
[70] FOOD AND DRUG ADMINISTRATION, GUIDANCE FOR INDUSTRY: GUIDE TO MINIMIZE MICROBIAL FOOD SAFETY HAZARDS OF MELONS; DRAFT GUIDANCE (2009).

water disinfectant at sufficient concentration to reduce the potential for cross contamination," and "[t]ransporting, storing, and using ice under sanitary conditions." These suggestions, if implemented, would ensure the ice was safe to use to cool and transport the melons without spreading human pathogens.

While the FDA does not explicitly list any scientific research as a reference for the proposed recommendations for top ice, the support is readily available. As early as 1849, when the cholera epidemic spread across London, doctor and scientist John Snow first announced his theory that dirty water and the disease were related.[71] He went on to publish *On the Mode of Communication of Cholera*, which further explained the ability of disease to spread.[72] Since that time, the science supporting the link between contaminated water and the spread of human pathogens has been thoroughly explored and developed. Today, the support for such a claim is undeniably supported by a large body of science.[73] All of the recommendations made in the section referring to top ice also include reference to clean water in order to stop the spread of pathogens. Numerous studies which support such a finding would easily pass the test set forth by the *Daubert* case. Therefore, the FDA could easily refer to this commonly accepted knowledge as a scientific basis for rules promulgated under the FSMA. It would not be necessary for the agency to provide specific studies or articles making the connection.

Once again, just as with wildlife, the recommendations in the section are all supported by science, but they lack specificity in application. One of the suggestions states the farmer or

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[71] Rita R. Colwell, *Infectious disease and environment: cholera as a paradigm for waterborne disease*, INTERNATIONAL MICROBIOLOGY VOL.7 n.4 (2004), *available at* http://scielo.isciii.es/scielo.php?pid=S1139-67092004000400008&script=sci_arttext.
[72] *Id.*
[73] *See e.g.*, William A. Rutala & David J. Weber, *Water as a Reservoir of Nosocomial Pathogens*, INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY VOL. 18, NO. 9 at 609-616 (1997); Ronnie B. Levin, Paul R. Epstein, Tim E. Ford, Winston Harrington, Erik Olson & Eric G. Reichard, *U.S. Drinking Water Challenges in the Twenty-First Century*, ENVIRONMENTAL HEALTH PERSPECTIVES VOL. 110, SUPPLEMENT 1: REVIEWS IN ENVIRONMENTAL HEALTH 2002, at 43-52 (2002).

packager should "[e]nsur[e][] that the water used to make ice is of sufficient microbial quality for its intended use."[74] The document goes no farther, however, to specify what quality of water is sufficient. Many different standards for water quality exist at the federal level. For example, the EPA lists different levels of water quality for recreation, aquatic life, agriculture and industry uses, and public water.[75] In addition, there are specific levels required for drinking water, which differs depending on the contaminant being measured or the state where the water is used.[76] None of these different standards, however, are mentioned in the guidance document. Given this, it makes it virtually impossible for a producer to know exactly which water quality standard to follow when attempting to comply with the guidance document.

The other recommendations for top ice also contain the same problem of generality. Another suggestion by the FDA for making sure ice used will not spread pathogens recommends "[u]sing ice that contains a water disinfectant at sufficient concentration to reduce the potential for cross contamination."[77] However, nowhere in the document does the agency explain what concentration of disinfectant is sufficient. Nor does it explain how much the potential for cross contamination must be reduced in order for the producer to be in compliance. The FDA also recommends "[t]ransporting, storing, and using ice under sanitary conditions."[78] Again, the guidance document does not define or clarify what conditions are considered sanitary. In each example, the producer must make some type of guess as to the meaning of the document's language. In such a case, assumptions might be entirely wrong. Therefore, while the

[74] FOOD AND DRUG ADMINISTRATION, GUIDANCE FOR INDUSTRY: GUIDE TO MINIMIZE MICROBIAL FOOD SAFETY HAZARDS OF MELONS; DRAFT GUIDANCE (2009).
[75] EPA Establishment of Water Quality Standards, 40 C.F.R. §131 (1992).
[76] EPA National Drinking Water Standards, 40 C.F.R. § 141 (1975); EPA National Primary Drinking Water Regulations Implementation, 40 C.F.R. § 142 (1998).
[77] FOOD AND DRUG ADMINISTRATION, GUIDANCE FOR INDUSTRY: GUIDE TO MINIMIZE MICROBIAL FOOD SAFETY HAZARDS OF MELONS; DRAFT GUIDANCE (2009).
[78] *Id.*

recommendations put forth in the guidance documents are based on scientific data and research, from a wide pool of such information, they still lack any true guidance for compliance.

The guidance document for melons also includes references to science that is not quite as historical as waterborne illness, but nonetheless is supported by extensive scientific research. Much of the guidance document is dedicated to risks associated with the melon's rind during harvest. Included in the document are recommendations for cantaloupes' stem scars and maturity, direct melon-to-ground contact, mechanical damage, and multiple harvests.[79] The introduction to the section explains that melons with netted rinds are more associated with human illnesses than melons with smooth rinds.[80] Further, human pathogens found on netted rinds "may adhere to, survive on, and be more difficult to eliminate…."[81] Within the guidance document, five scientific studies are listed to support the connection between melon rinds and human pathogens.[82] In addition, there is a large body of research connecting certain aspects of the rind with higher risks of contamination.[83] On a whole then, the FDA's recommendations to implement procedures and practices to minimize the risk of any contamination of melons by human pathogens is important and, certainly, scientifically based. Since the pathogens are difficult to remove, the suggestion seeks to prevent contamination before it happens. Using the support listed in the guidance document and the larger body of works making the connection, the recommendations may easily meet the *Daubert* standard. Therefore, if the FDA's suggestions in

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[79] *Id.*
[80] *Id.*
[81] *Id.*
[82] *Id.*
[83] *See e.g.*, B.A. Del Rasario and L.R. Beuchat, *Survival and Growth of Enterhemorrhagic Escherichia coli O157:H7 in Cantaloupe and Watermelon,* JOURNAL OF FOOD PROTECTION, 1994, at 105-107; Annous, B.A., A. Burke, and J.E. Sites, *Surface pasteurization of whole fresh cantaloupes inoculated with Salmonella poona or Escherichia coli,* JOURNAL OF FOOD PROTECTION, 2004, at 1876-85; J. Behrsing, et al., *Survival of Listeria innocua, Salmonella salford and Escherichia coli on surface of fruit with inedible skin,* POSTHARVEST BIOLOGY AND TECHNOLOGY, 2002, at 249-256.

the guidance document were promulgated under the FSMA, they would certainly meet the statutory requirement of being science-based.

Once again, however, although the recommendations are firmly supported by scientific evidence, the practical implementation is lacking. For example, the FDA recommends "[e]valuating soil amendments where melons directly contact soil."[84] Just as in the other sections, the suggestion by the FDA fails to explain what soil amendments are important to consider. It does not specifically mention when soil additives would be considered high risk, or when melons need to be discarded due to exposure. Overall, the recommendation fails to give actual guidance to farmers for implementing the safety procedures. Likewise, the document recommends farmers "[e[valuat[e][] the type of irrigation (such as furrow or drip) used to minimize soil wetting where melons directly contact soil."[85] Just as in the other examples, the guidance document does not clarify what level of ground moisture is acceptable or reasonable when in direct contact with the melons. Nor does it suggest types of irrigation that may be better designed to minimize the associated risks. Attempting to implement such a recommendation would be difficult when only minimal guidance is actually given. Thus, even when the rules are easily supported by countless studies, data, and research, the actual recommendation is not always specific, descriptive, or clarified.

While the scientific data may be incomplete regarding the best methods or practices for preventing food borne illnesses associated with melons, the FDA does have the ability to give more specific information. For example, the guidance document warns that removing pathogens from the melon's rind may be very difficult, and suggests implementing washing procedures that

[84] FOOD AND DRUG ADMINISTRATION, GUIDANCE FOR INDUSTRY: GUIDE TO MINIMIZE MICROBIAL FOOD SAFETY HAZARDS OF MELONS; DRAFT GUIDANCE (2009).
[85] *Id.*

will minimize the risk.[86] As with the other recommendations given, however, specific information is lacking. While there is no foolproof way of completely cleaning the rind, the FDA cites research in the guidance document that does give more specific direction. In a study conducted by the USDA, it was found that "sanitizing with chlorine or hydrogen peroxide has the potential to reduce or eliminate the transfer of L. monocytogenes on melon surfaces to fresh-cut pieces during cutting."[87] The study also provides some direction to the levels of chlorine or hydrogen peroxide necessary to reduce the risk.[88] Again, while scientific discovery of more effective cleaning methods may be forthcoming, including the information described in the study would at least provide some guidance to farmers and packagers attempting to comply with the recommendations. Specificity would allow producers to take preventative steps for food safety, which support the goals of the FSMA. When the FDA does have more specific information then, it should be reflected in the recommendations or rules.

The guidance documents for leafy greens, tomatoes, and melons all make recommendations for limiting and preventing the spread of human pathogens. If the guidance documents were promulgated under the FSMA, the recommendations contained in them would have to meet the science-based standard required for rules regarding fresh produce. Many, if not all, of the FDA's recommendations set forth in the guidance document for melons could probably meet the standard set out by the *Daubert* court. Likewise then, the recommendations would probably meet a science-based standard under the FSMA. Moreover, much of the guidance documents are derived from areas of science that are generally accepted and well documented. For example, there have been numerous studies and research supporting the link

[86] *Id.*
[87] D.O. Ukuku and W. Fett, *Behavior of Listeria monocytogenes inoculated on cantaloupe surfaces and efficacy of washing treatments to reduce transfer from rind to fresh-cut pieces*, JOURNAL OF FOOD PROTECTION 65(6) at 924 – 930 (2002).
[88] *Id.*

between animals and the spread of human pathogens. The same is true of water acting as a conduit for illness. However, although the recommendations provided in the guidance documents can easily meet a science-based requirement, they do not offer much guidance to those required to implement them. The recommendations are broad, general, and not at all detailed. Even if a farmer or packager attempts to comply with them, it is difficult to know what level of compliance is necessary, or even what standards the FDA would use to judge compliance. Currently, the recommendations are too general for growers to even begin to implement them, let alone anticipate the costs and changes necessary for compliance. While the generalities may ensure that the recommendations are indisputably supported by science, they are not written practically. Before being promulgated under the FSMA, the guidance documents must be clarified and rewritten to be more specific. Only then can the recommendations be effective in preventing the spread of human pathogens and be practically implemented consistent with the goals of the FSMA.

IV. Conclusion

An examination of the scientific process shows that the scientific community, when necessary, may rely on incomplete science to recognize causation. In reality, mere associations may be proof enough of certain connections, within which scientists feel comfortable drawing conclusions, even if the details still need to be worked out. For example, science recognized a link between smoking and cancer long before it was fully understood how or why the correlation occurred. In order to fully understand observations and associations, further research is constantly being conducted. The methodologies used to test theories, hypotheses, and ideas must conform with reliable techniques that are generally accepted within the scientific community. As the research is conducted, gaps in understanding are filled and previous knowledge is

supplemented with new information. This framework provides a backdrop through which regulations and rules may be implemented as preventative measures. As the scientific knowledge increases, the preventative actions may become more precise and accurate.

Although scientific research may be used before the body of understanding is complete, legal analysis requires some indicia of reliability. In order to adjudicate questions of science, the United States Supreme Court articulated a set of standards specifically to be used for the testimony of expert witnesses. The Supreme Court did not require such a high standard that only complete scientific knowledge could be employed. Rather, the factors, as described in the *Daubert* case, lay a framework for lower courts to determine whether the science being used to support expert testimony is reliable. As a result, courts do not actually have to decide whether the supporting science is correct; the judge only has to make a determination of reliability. When these factors are applied, they provide a scheme for deciding that normal scientific procedures have been implemented. Therefore, the judiciary is able to avoid coming to scientific conclusions, but may still protect the integrity of evidence. Deference is given to the scientific community as a whole, and the methods and procedures typically used for normal science. Extending the holding of *Daubert* to apply the factors to a science-based standard for the fresh produce rules promulgated under the Food Safety and Modernization Act (FSMA) creates a framework for determining whether the rules are properly supported by science.

When applying the standards for credible science to the Food and Drug Administration's (FDA) guidance documents for Generally Accepted Practices for melons, leafy greens, and tomatoes issued in 2009, the recommendations easily meet the factors. Many of the suggestions in the guidance documents are supplemented by research, studies, and data which support them. In addition, the guidance documents are mostly based on generally accepted scientific

knowledge. For example, it has long been known that animals, insects, and other forms of wildlife can carry diseases. Likewise, it has been recognized for centuries that water may act as a conduit for pathogens. The FDA's guidance documents utilize these vast areas of science to craft the recommendations included in them. Therefore, not only do the referenced materials meet the *Daubert* factors, there are numerous credible sources that would support the FDA's conclusions. A person challenging the recommendations would be hard-pressed to argue that the science was incomplete, not available, or just wrong. Therefore, the agency would have no problems promulgating the recommendations into rules, despite the science-based requirement of the FSMA.

However, the recommendations in the guidance documents are so firmly supported by science simply because they are so vague. Each of the listed suggestions by the FDA within the guidance documents can be easily supported by large general bodies of scientific evidence. For example, the guidance documents advise farmers to consider the weather, soil, and topology of the land before planting melons. However, the FDA fails to describe what types of factors are problematic, or when those factors render a field unsafe for growing and harvesting melons. Or consider the recommendations that indicate sufficient disinfectant should be mixed with the water used to make ice. Even though the application of adding the disinfectant would be very technical and precise, the guidance documents fail to provide any indication of how much is enough. Overall, these recommendations make it extremely difficult, if not impossible, to implement. Even if a farmer or packager makes an educated choice on what standard should be followed for compliance, the assumption might be incorrect. Further, the generalities in the recommendations make it extremely difficult for producers to anticipate future costs. It also prevents them from implementing these important preventative measures prior to the

promulgation of rules under the FSMA. Before being enacted as regulations which must be followed, it is essential that the FDA clarifies and describes what is required.

The scientific standard for rules promulgated under the FSMA for fresh produce was meant to be a control mechanism against overzealous regulations without any measure of researched scientific support. By that same token, it ensures that necessary regulations for food safety are promulgated to prevent well documented problems in our food system. While scientific evidence is not always complete, there is a large body of established scientific understanding which allows us to move forward with fighting back against the spread of food borne illnesses. Any rules promulgated under the FSMA for fresh produce should not only be science-based however, they should also be clear and specific enough to be practically planned for and implemented. This will ensure that the goals of the FSMA, specifically to prevent the spread of human pathogens, will be met. While the agricultural industry may feel a science-based standard operates as a shield or protection from outlandish regulations, the real problem is the lack of specificity. The FSMA was a bold step in improving the safety of every aspect of our food supply. As well, the change in focus toward preventing pathogen outbreaks, instead of just reacting to them, was an important change in perspective. As our understanding of the natural world around us improves, our ability to prevent human illnesses and increase food security and safety also progresses.

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