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A PROPOSAL FOR FDA LABEL REGULATIONS AND UNIFORM CERTIFICATIONS FOR ORGANIC NON-FOOD AND “NATURAL” PRODUCTS

*Allyson Bartolomeo**

In 2013, a consumer fraud class action was filed against Huggies’ manufacturer Kimberly-Clark.¹ The plaintiffs alleged that they had purchased the company’s “Natural Care” baby wipes at a premium price, believing the product was a “natural, [and] relatively safe” alternative to traditional wipes.² Contrary to their assumptions, the consumers later discovered that the wipes contained sodium methylparaben³—a preservative banned in the European Union,⁴ which has potential links to breast cancer, tumor growth, male infertility, and skin irritation⁵—and methylisothiazolinone⁶—another preservative, restricted in cosmetics use in Canada and Japan,⁷ which the Environmental Protection Agency (EPA) considers to be “highly acutely toxic when applied dermally,”⁸ and has been linked to rising rates of recalcitrant dermatitis in pediatric populations.⁹

I. INTRODUCTION

Consumers rely on labels in making decisions about what products to put in and on their bodies,¹⁰ to use in their homes, and to provide for their families.¹¹ When the market for organic products began growing in the United States, states soon after stepped in with regulations to ensure product transparency for consumers.¹² Although today the United States Department of Agriculture (USDA) has taken on the role of creating and enforcing uniform, national regulations for organic

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1. *Jou v. Kimberly-Clark Corp.*, No. C-13-03057 JSC, 2013 U.S. Dist. LEXIS 173216, at *1 (N.D. Cal. Dec. 10, 2013).

2. *Id.* at *3–4.

3. *Id.* at *3.

4. *Id.*

5. Traci Joy, *What Are The Dangers of Methylparaben*, LIVESTRONG (Apr. 15, 2015), <http://www.livestrong.com/article/21581-dangers-methylparaben/>.

6. *Jou*, 2013 U.S. Dist. LEXIS 173216, at *3.

7. *Id.*

8. *R.E.D. Facts, Methylisothiazolinone*, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 1, 2 (Oct. 1998), https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/fs_G-58_1-Oct-98.pdf.

9. See generally Megan J. Schlichte & Rajani Katta, *Methylisothiazolinone: An Emergent Allergen in Common Pediatric Skin Care Products*, 2014 DERMATOLOGY RES. & PRAC. 1 (2014).

10. See Donna M. Bryne, *Cloned Meat, Voluntary Food Labeling, and Organic Oreos*, 8 PIERCE L. REV. 31, 35–37 (2009).

11. See generally *id.* at 35.

12. See Michelle T. Friedland, *You Call That Organic? – The USDA’s Misleading Food Regulations*, 13 N.Y.U. ENVTL. L.J. 379, 382 (2005).

production,¹³ many gaps and uncertainties still exist within the organic market. Somehow, the market for personal care products—products which can have more direct effects on the body than food products¹⁴—has become the forgotten step-child of the organic industry. Additionally, the market for natural products—which goes hand-in-hand with the organic industry—operates with minimal regulation of the word “natural” on labels for both food and non-food products.¹⁵

Insufficient standards are imposed to ensure that consumers looking to avoid harmful ingredients are not misled when choosing products labeled as “natural” or “organic.” These inadequately regulated markets can lead to physical harm to consumers,¹⁶ as well as deceitful marketing and unfairly hiked prices.¹⁷

The purpose of this article is to shed light on consumer deception in labeling that exists in the organic and natural food markets, despite current labeling requirements and prohibitions, and to propose regulations which would create more transparency and further the purposes of labeling statutes.¹⁸ This article urges the USDA and the Food and Drug Administration (FDA) to implement clear standards for the use of the word “organic” on non-food products, to develop certification for what constitutes a product being “natural,” and to apply these standards through uniform regulations.

This article first discusses the history of the National Organic Program (NOP) and the current standards it uses for regulating food as well as qualifying non-food products. Next, it explains the problems that arise from the FDA’s allowance of private certifying agencies and the use of their seals on product labels. It then explores the regulations that exist for marketing and labeling a product as “natural,” and the ambiguities that result from the lack of a definition of what qualifies a product as “natural.” This article aims to reveal the deception that can result from these lax regulations, as well as the inequities such standards cause to farmers and manufacturers. Finally, this article proposes new guidelines and definitions for the FDA to implement in order to alleviate these issues and create a more transparent market. These suggestions include: the creation of uniform, FDA-certified regulations to replace the sea of independent, private certifications that currently exist; the implementation of a “natural” definition and certification requirements,

13. Marian Burros, *U.S. Imposes Standards for Organic-Food Labeling*, N.Y. TIMES, Dec. 21, 2000, <http://www.nytimes.com/2000/12/21/us/us-imposes-standards-for-organic-food-labeling.html>.

14. See generally *About Skin: Your Body's Largest Organ*, AM. ACAD. OF DERMATOLOGY, <https://www.aad.org/public/kids/skin> (last visited Nov. 19, 2017) (explaining that the skin is the body’s largest and fastest growing organ).

15. “Natural” on Food Labeling, FDA, <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm456090.htm> (last visited Nov. 26, 2017).

16. See *Jou*, 2013 U.S. Dist. LEXIS 173216 at *2–3.

17. See *id.* at *3–4.

18. This article does not attempt to further any idea about whether or not using and consuming only organic or only natural products is better than using conventional products. This article also does not inquire into the health or environmental implications associated with GMOs, be there any. It is only advocating for the implementation of more clear and transparent labeling regulations that allow consumers to be aware of what is in the products they use and eat, and the processes which were used to create these items.

including a list of acceptable and unacceptable ingredients; and a mandated “GMO” or “non-GMO” label on every product which is certified as “natural.”

II. BACKGROUND AND HISTORY

The Pure Food and Drugs Act of 1906 was the first federal labeling law in the United States.¹⁹ The Act prevented consumer deception by prohibiting the use of false or misleading statements on food labels.²⁰ Labeling creates transparency between the producer and consumer, which leads to the elimination of deception and allows the consumer to act in his or her own best interest.²¹ Given the proper information and the choice, it is presumed that the consumer will make purchases that maximize utility or welfare.²² Modern labeling laws, such as the Federal Food, Drug, and Cosmetic Act (FDCA),²³ eliminate deception through both the prohibition of false statements and the requirement that certain, specific information be included on labels.²⁴

A. The Birth of the Organic Industry in America

In 1942, Jerome Rodale, a Pennsylvanian farmer, published the first issue of Organic Farming and Gardening magazine, and the United States’ organic industry was born.²⁵ Rodale believed that by foregoing the inventions and chemicals of modern science in farming, and using traditional composting methods instead, healthier crops would be produced and fertile soil could be preserved.²⁶ Though his ideas were first met with skepticism and ridicule, Rodale’s persistent efforts—coupled with Rachel Carson’s publication of *Silent Spring* in 1962²⁷—led to more widespread rejection of pesticide and agrochemical use in food production.²⁸ Farmers who followed Rodale began selling organic food beginning in the 1970s.²⁹ In 1973, Oregon passed the first organic certification law regulating organic food labeling.³⁰ The statute was passed in response to allegations that some farmers were fraudulently marketing “non-organic” food as “organic” in hopes of capitalizing off the recent trend and misleading consumers to pay higher prices for conventional food.³¹ Other states followed Oregon’s lead, and by 1990, twenty-one other states

19. Bryne, *supra* note 10, at 35.

20. *Id.*

21. *Id.*

22. *Id.*

23. 21 U.S.C. § 301 (2016).

24. Bryne, *supra* note 10, at 38.

25. Friedland, *supra* note 12, at 381; Chenglin Liu, *Is “USDA Organic” a Seal of Deceit? The Pitfalls of USDA Certified Organics Produced in the United States, China and Beyond*, 47 STAN. J. INT’L L. 333, 336–37 (2011).

26. Liu, *supra* note 25, at 336.

27. Friedland, *supra* note 12, at 381.

28. *Id.*s largest and fastest growing organ)s these markets.ead to a more transparent market for consumers, and eliminate deception 676767

29. *Id.*

30. *Id.* at 382.

31. *Id.* at 381–82.

had enacted similar regulations.³² However, the regulatory requirements of each state differed,³³ and while the regulatory schemes worked well within each individual state, the conflicts between what qualified as “organic” in one state compared to another gave rise to problems with interstate commerce and were confusing to consumers.³⁴

During this time period, in order to comply with individual state laws, farmers and producers were forced to either create different labels for the exact same products, or else vary their production methods for the same foods, in accordance with the regulations in each state in which they were selling.³⁵ Retailers and distributors became reluctant to purchase and carry organic foods for fear of the possibility of selling items that did not satisfy the state-by-state regulations.³⁶ The food that did make it to the shelves carried multiple, different state certifications, all with different meanings.³⁷ The variation in regulations at that time was so wide that one state’s products could be deemed organic for containing only 20% organically-grown ingredients, while another state would require 100% organically-grown ingredients for certification.³⁸

B. The Development of National Standards for Organic Food

In response to the desire for uniform labeling standards, Congress passed the Organic Foods Production Act (OFPA) in 1990.³⁹ The act states in relevant part:

It is the purpose of this chapter—

- (1) to establish national standards governing the marketing of certain agricultural products as organically produced products;
- (2) to assure consumers that organically produced products meet a consistent standard; and
- (3) to facilitate interstate commerce in fresh and processed food that is organically produced.⁴⁰

To achieve these goals, OFPA requires that the Secretary of Agriculture “establish an organic certification program for producers and handlers of agricultural products that have been produced using organic methods.”⁴¹ OFPA also lists

32. *Id.* at 382.

33. Friedland, *supra* note 12, at 382.

34. Liu, *supra* note 25, at 337.

35. *Id.*

36. Kenneth C. Amaditz, *The Organic Foods Production Act of 1990 and Its Impending Regulations: A Big Zero for Organic Food?*, 52 FOOD & DRUG L.J. 537, 539 (1997).

37. *Id.*

38. *Id.*

39. Liu, *supra* note 25, at 337; 7 U.S.C. §§ 6501–22 (2012).

40. 7 U.S.C. § 6501 (2012).

41. 7 U.S.C. § 6503 (2012).

requirements and national standards for organic production, and permits states to establish their own, more restrictive organic certification program, so long as it satisfies the requirements of OFPA and is approved by the Secretary of Agriculture.⁴²

Over the next decade, while the national standards were being written, proposed, and revised, the organic market continued to boom.⁴³ Domestic organic food sales increased by 20% annually throughout the 1990s, reaching six billion dollars in 1999.⁴⁴ It took seven years for the first set of proposed national standards to be completed, and the revised and final rules were not complete until December of 2000.⁴⁵ The regulatory framework that resulted is the National Organic Program (NOP), which is part of the Agricultural and Marketing Service of the USDA.⁴⁶ If an agricultural product meets the national standards of the NOP, then the product's label can include the USDA organic seal.⁴⁷ If an "organic" operation violates the regulations, they are subject to enforcement actions, "which can include financial penalties or suspension/revocation of [its] organic certificate."⁴⁸

III. CURRENT REGULATIONS

A. Organic Certification

Today, NOP regulations for organic certification focus on both the ingredients in the product and process of production.⁴⁹ To obtain organic certification and be permitted to use the USDA Organic seal on a product label, a product must receive approval from a USDA-accredited certifying agent.⁵⁰ The NOP uses four levels of categorization for labeling certified products: 1) if a product is completely organic, it may use the USDA organic seal and/or make a "100% organic" claim on its label; 2) a product composed of 95% organic ingredients may still use the seal if the 5% of ingredients that are conventional are on a list of allowed ingredients; 3) if a product is made up of at least 70% organic ingredients, and the ingredients that make up the other 30% are on the list of allowed ingredients and not produced using excluded methods, the product label may not use the USDA organic seal, but can make a "made with organic [X]" claim, which lists up to three ingredients or categories; and 4) a product composed of less than 70% organic ingredients may not use the USDA

42. 7 U.S.C. §§ 6503–07 (2012).

43. Burros, *supra* note 13.

44. *Id.*; Jessica Ellsworth, The History of Organic Food Regulation (2001) (unpublished third year paper, Harvard University) (on file with Digital Access to Scholarship at Harvard).

45. Friedland, *supra* note 12, at 382–84.

46. *Id.* at 388; *Nat'l Organic Program*, USDA, AGRIC. MKTG. SERV., <https://www.ams.usda.gov/about-ams/programs-offices/national-organic-program> (last visited Nov. 19, 2017).

47. *Id.*

48. *Organic Certification and Accreditation*, USDA, AGRIC. MKTG. SERV., <https://www.ams.usda.gov/services/organic-certification> (last visited Nov. 19, 2017).

49. *See Organic Production & Handling Standards*, USDA, AGRIC. MKTG. SERV., <https://www.ams.usda.gov/publications/content/organic-production-handling-standards> (last visited Nov. 26, 2017).

50. *Id.* at 1.

organic seal and must not use the word organic on the main display panel, but may state certified organic ingredients in the ingredient list.⁵¹

B. Non-Food and Non-Agricultural Products

While the standards imposed today for agricultural food products are clear, much less can be said about non-food products derived from non-agricultural ingredients. As the organic food market grows, so does the market for other organic items, such as personal care items, cosmetics, household cleaners, and clothing.⁵² In 2015, organic product sales in the United States—including both food and non-food items—reached \$43.4 billion.⁵³ The non-food organic product sales increased 13% from the previous year, making up \$3.6 billion of the total.⁵⁴

During final deliberations of the regulations in 2000, when asked whether the NOP regulations included, “certification standards for cosmetics, body care products, and dietary supplements,” the USDA clarified that, “[p]roducers and handlers of agricultural products used as ingredients in cosmetics, body care products, and dietary supplements could be certified under these regulations . . . [but t]he ultimate labeling of cosmetics, body care products, and dietary supplements, however, is outside the scope of these regulations.”⁵⁵ Since then, the USDA has fluctuated on their position.⁵⁶ In a 2002 policy statement, the Department again explained that some cosmetics may qualify for certification because they may contain agricultural products.⁵⁷ Less than two years later, in 2004, the USDA issued a guidance statement that differed from what it had previously stated.⁵⁸ The Department stated that because it lacks regulatory authority over these types of products, producers of cosmetic and personal care items could not seek voluntary certification, even for agricultural products.⁵⁹ Just months later, it changed its position again, reverting to its original statement from 2000.⁶⁰ In its most recent statement, the USDA kept the more inclusive scheme.⁶¹ So, as long as a personal care, body care, or cosmetic product “contains or is made up of agricultural ingredients, and can meet the USDA/NOP organic production, handling, process and labeling standards, it may be eligible to be certified under the NOP regulations.”⁶²

51. *Labeling Organic Products*, USDA, AGRIC. MKTG. SERV., <https://www.ams.usda.gov/sites/default/files/media/Labeling%20Organic%20Products.pdf> (last visited Nov. 19, 2017).

52. *See OTA Calls for Federal Policies to Ensure “Organic” Always Means “Organic,”* ORGANIC TRADE ASS’N, <https://www.ota.com/news/press-releases/19336> (last visited Nov. 19, 2017).

53. *Id.*

54. *Id.*

55. National Organic Program, 65 Fed. Reg. 80,557 (Dec. 21, 2000).

56. *See generally* All One God Faith, Inc. v. Hain Celestial Group, Inc., No. C 09-03517 JF (HRL), 2011 U.S. Dist. LEXIS 108269, at *13 (N.D. Cal. Sept. 20, 2011).

57. *Id.*

58. *Id.*

59. *Id.*

60. *Id.*

61. *See Cosmetics, Body Care Products, and Personal Care Products*, USDA, AGRIC. MKTG. SERV., 1 (Apr. 2008), <https://www.ams.usda.gov/sites/default/files/media/OrganicCosmeticsFactSheet.pdf>.

62. *Id.*

Following the same requirements that apply to food items, “[t]he operations which produce the organic agricultural ingredients, the handlers of these agricultural ingredients, and the manufacturer of the final product must all be certified by a USDA-accredited organic certifying agent.”⁶³

The problem with allowing only wholly-agricultural products to obtain permission to use the USDA organic seal is that cosmetic, body care, and personal care items that are not made entirely of agricultural ingredients, but are made with less synthetic, less processed, or fewer chemical ingredients, have no option for a special certification.⁶⁴ The “FDA does not define or regulate the term ‘organic,’ as it applies to cosmetics, body care, or personal care items.”⁶⁵ Additionally, “[u]nder the Federal Food, Drug, and Cosmetic Act . . . cosmetic products and ingredients, other than color additives, do not need FDA approval before they go on the market.”⁶⁶

Instead, companies that produce cosmetics, body care, and personal care items are authorized to apply for certifications from private, third-party certifying agencies and display those agencies’ seals on their product labels.⁶⁷ The certifications may include “foreign organic standards, eco-labels, earth friendly, etc.,”⁶⁸ but the NOP does not regulate what exactly these seals certify, the process for obtaining certification, or how the third-party agency ensures that standards of the seal are being met.⁶⁹ The use of varying standards like this is reminiscent of the days before the OFPA, when consumers were tasked with deciphering what each individual emblem printed on packages in the grocery store meant.⁷⁰ If a modern consumer sees an “earth friendly” seal on a product’s label, she may think she knows what the symbol signifies, but what qualifies as “earth friendly” according to agency A may differ greatly from the standards that agency B requires to be met to use the same phrase. Even if the consumer takes the time to research and understand what each seal certifies before making a purchase, additional uncertainties can still exist. The consumer will either trust that these certifications mean what they state—at the risk of being deceived—or the consumer will need to spend additional time researching the reputation of the private label.

In October 2016, the Federal Trade Commission (FTC) and USDA co-hosted a roundtable discussion regarding consumers’ beliefs and perceptions regarding “organic” claims for products which fall outside of the USDA’s NOP regulations.⁷¹ The meeting also focused on approaches to improve organic claims for non-

63. *Id.*

64. *See id.*

65. *Id.*

66. *Parabens in Cosmetics*, UNITED STATES FOOD AND DRUG ADMIN., <https://www.fda.gov/Cosmetics/ProductsIngredients/Ingredients/ucm128042.htm> (last visited Nov. 19, 2017).

67. *Cosmetics, Body Care Products, and Personal Care Products*, *supra* note 62, at 2.

68. *Id.*

69. *See id.*

70. *See Liu*, *supra* note 25, at 337.

71. *Consumer Perceptions of “Organic” Claims Roundtable*, FED. TRADE COMMISSION, <https://www.ftc.gov/news-events/events-calendar/2016/10/consumer-perceptions-organic-claims-ftc-usda-roundtable> (last visited Nov. 19, 2017).

agricultural products, as well as ways to avoid deception.⁷² Currently, there is no plan to reform this area.

C. “Natural” On Food Product Labels

In the wake of the success of the organic market, the word “natural” is now being used to market products as well.⁷³ Just like the problems that arose with the initial use of organic claims on labels, the minimal rules that govern the use of the word “natural” are leading to claims of fraud and deceit by consumers.⁷⁴ The FDA expressly states that it has not developed a definition for use of the word “natural” or any of its derivatives on food labels.⁷⁵ The Administration explained that it has yet to define the word because from a food-science perspective, once a food has been processed into a different final product, it is no longer a product from the Earth.⁷⁶ The FDA also explains that if a food does not include added color, artificial flavors, or any synthetic substance, it does not object to describing the food as “natural.”⁷⁷

IV. CONSUMER PERCEPTIONS

A. The Meaning of “Natural”

Current research shows that the consumer perceptions about the word “natural” on food labels vary widely.⁷⁸ The Organic Trade Association (OTA) has conducted an annual consumer study on families’ organic attitudes and beliefs since 2009.⁷⁹ The 2010, 2013, and 2015 versions of these studies included specific questions regarding perceptions about the word “natural.”⁸⁰ According to the OTA, the 2015 results, which surveyed over 3,400 parents, revealed in part that:

71% of respondents think that natural products are “grown without the use of toxic pesticides or fertilizers,” 70% believe that they are “produced without the use of genetically modified organisms” and 54% think that they are “inspected, certified and enforced according to government standards.” 82% of those surveyed admitted that they confused organic and natural products at least some of the time.⁸¹

Similarly, a survey conducted by the Consumer Reports National Research Center in 2015 concluded that:

72. *Id.*

73. See Nicole Negowetti, *Food Labeling Litigation: Exposing Gaps in the FDA’s Resources and Regulatory Authority*, GOVERNANCE STUDIES AT BROOKINGS, 1, 6 (2014), https://www.brookings.edu/wp-content/uploads/2016/06/Negowetti_Food-Labeling-Litigation.pdf.

74. See Letter from Gwendolyn Wyard to Division of Dockets Management, Food and Drug Administration (May 10, 2016), http://ota.com/sites/default/files/indexed_files/NaturalClaims_Comments_Final.pdf.

75. “Natural” on Food Labeling, *supra* note 15.

76. *Id.*

77. *Id.*

78. See Wyard, *supra* note 74, at 2.

79. *Id.* at 4.

80. *Id.*

81. *Id.*

most consumers think that the natural label on meat and poultry currently means that no artificial ingredients or colors were added to the meat or poultry (65%), no artificial growth hormones were used (64%), the animals' feed contained no artificial ingredients or colors (61%), the animals' feed contained no GMOs (59%), and no antibiotics or other drugs were used (57%).⁸²

Overall, a comparison of what consumers believe "natural" to mean, against the vague FDA statement about what is not unnatural, demonstrates that consumers generally believe that a package labeled "natural" contains products regulated at a much higher standard than they really are.

B. Lawsuits Resulting from a Lack of Definition

The varying beliefs and uncertainty as to what constitutes a "natural" product has led to a surge in class action lawsuits brought by consumers against manufacturers who claim, through labeling, that their products are "natural," "all natural," or "100% natural."⁸³ For example, there is controversy about what processes are allowed in the production and ingredients of these products, whether or not a label must plainly disclose when a product is derived unnaturally, and whether genetically modified organisms (GMOs) are considered "natural." In 2011, a group of plaintiffs filed suit against Ben & Jerry's Homemade, Inc. on the basis that they were fraudulently misled by the "all natural" claims on one of the company's ice cream labels.⁸⁴ The plaintiffs contended that because the cocoa used in the ice cream had been processed with a man-made ingredient—potassium carbonate—it was not "natural" cocoa, and therefore, the product label was misleading.⁸⁵ In a suit against General Mills, Inc. filed in 2010, another group of plaintiffs alleged that they were misled by the company's Fiber One products that advertised "35% of your daily fiber" on their labels.⁸⁶ The discrepancy was just as much about what the label claimed, as well as what it failed to mention.⁸⁷ Although the labels did not state that the products were "natural," the plaintiffs claimed to be misled because the fiber referred to on the packaging was not "natural fiber," but instead, fiber derived from chicory root through a scientific extraction process.⁸⁸ A suit was brought against Conagra Foods, Inc. in 2015 by a group of citizens from eleven different states, who claimed that the company deceptively marketed its Wesson brand of cooking oils.⁸⁹ The oils, which contained the words "100% Natural" on their labels, were created using genetically engineered ingredients.⁹⁰ The

82. *Id.* at 5.

83. Richard M. Blau & Anna M. Wiand, *FDA's Next Action On Defining "Natural" For Food Labeling Purposes Remains Unclear*, LEXOLOGY, July 21, 2016, <http://www.lexology.com/library/detail.aspx?g=efaabaec-227f-43fd-9462-09396bd2a1eb>.

84. *Astiana v. Ben & Jerry's Homemade, Inc.*, No. C 10-4387 PJH, 2011 U.S. Dist. LEXIS 57348, at *2 (N.D. Cal. May 26, 2011).

85. *Id.*

86. *Turek v. General Mills, Inc.*, 754 F. Supp. 2d 956, 957 (N.D. Ill. 2010).

87. *Id.*

88. *Id.*

89. *In re Conagra Foods, Inc.*, 90 F. Supp. 3d 919, 939 (C.D. Cal. 2015).

90. *Id.*

United Nations considers any organism that has at least one inserted gene to be a GMO.⁹¹ While agricultural cross-breeding has been practiced for over 100 years, scientists in the 1990s began using biotechnology to isolate specific, desirable genes in one organism in order to introduce them into another organism's genes.⁹² Currently, the FDA has refused to take a position on whether genetically engineered products constitute "natural" foods or not.⁹³

Whether or not the plaintiffs in these types of suits are able to succeed on claims of deception generally depends on whether the labels would mislead a reasonable consumer under reasonable circumstances.⁹⁴ The lack of a federal definition of "natural," along with widely varying beliefs as to what constitutes a natural product, make the possibilities of what a "reasonable consumer" would think nearly endless.

C. FDA Inquiry into a Potential Definition for "Natural"

By 2015, the FDA had received at least three Citizen Petitions urging for a reattempt to define what is "natural."⁹⁵ Federal courts had also requested administrative determinations regarding whether or not foods made with genetically engineered ingredients or high-fructose corn syrup were qualified as "natural."⁹⁶ The Administration responded by restating their 1991 policy for use of the word "natural" on food labels, which states, "nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in that food."⁹⁷ It also clarified that "this policy was not intended to address food production methods, such as the use of pesticides, nor did it explicitly address food processing or manufacturing methods, such as thermal technologies, pasteurization, or irradiation,"⁹⁸ and that it, "did not consider whether the term 'natural' should describe any nutritional or other health benefit."⁹⁹

In response to the petitions, the FDA set up a comment period on Regulations.gov, and invited the public to respond to questions regarding whether or not it is appropriate to define "natural," and if so, how the term should be defined and how the appropriateness of its use on food labels should be determined.¹⁰⁰ Public comment requests like this are one of two ways the FDA initiates the notice and comment rulemaking procedure.¹⁰¹ After reviewing the comments, the

91. Stephanie Amaru, *A Natural Compromise: A Moderate Solution to the GMO & "Natural" Labeling Disputes*, 69 FOOD DRUG L.J. 575, 575 (2014).

92. *Id.*

93. *See In re Conagra Foods, Inc.*, 90 F. Supp. 3d at 1020.

94. *Id.* at 992–93.

95. "Natural" on Food Labeling, *supra* note 15.

96. *Id.*

97. *Id.*

98. *Id.*

99. *Id.*

100. *Id.*

101. Amaru, *supra* note 91, at 584–85.

Administration will update or propose a rule, issue a final rule, or end the process without making any changes or additional rules.¹⁰²

The period for commenting ended on May 10, 2016.¹⁰³ Since that time, the FDA has not commented further on what it plans to do with the comments it has received, and still appears to be considering whether or not it will begin to regulate the word.¹⁰⁴

V. Proposal

In order to provide a more transparent market to consumers and create an industry with more certainty, the FDA needs to implement hard and fast rules regarding products which include the word “natural” on their labels and for non-food products to obtain an organic seal. As was evident during the birth of the organic industry in America, without clear, uniform regulations, the market place becomes confusing for consumers,¹⁰⁵ and limits their ability to make choices that best serve their wants and needs. It also becomes easier for producers to mislead and deceive consumers, whether it be purposeful or accidental.¹⁰⁶ Until the FDA sets such standards, consumers will continue to be misled into buying products that may be produced with ingredients they never intended to purchase. A lack of trust about what the emblems and words on labels signify will render obtaining permission to use these seals on products useless to producers and farmers, because consumers will no longer believe that the claim holds any weight.

A. Body Care, Personal Care, and Cosmetics Certifications

Although allowing private, third-party certifications on products which fall outside the USDA’s current organic certification requirements seems useful in theory, in practice it can create more confusion for consumers and increases the possibility of deceit.¹⁰⁷ While certifications and seals inform consumers about the products they are considering purchasing, creating a market with too many different seals, all with different meanings, certification requirements, and levels of trustworthiness can create more confusion.¹⁰⁸ Further, it is possible and likely that a consumer may not realize that the seals he or she sees on product labels may not have been awarded by a government agency, but rather, by independent companies.¹⁰⁹

In order to alleviate these problems and this uncertainty, the FDA should no longer allow products to be certified by private, third-party agencies. Ideally, the FDA should conduct studies to find out what types of independent certifications are being used in today’s market and what types of information and assurances

102. *Id.* at 585.

103. “Natural” on Food Labeling, *supra* note 15.

104. *Id.*

105. *See* Liu, *supra* note 25, at 337.

106. *Id.* at 377–78.

107. *See id.* at 337.

108. *See id.*

109. *See generally* Amaditz, *supra* note 36, at 558.

consumers wish to see through product labels. Using this information, the Administration should come up with its own categories of certifications and standards to be met in order for a product to receive them. Just like in the organic industry, in order to be able to use these words and certification seals on a label, a product should have to be approved by an FDA-certified agency.¹¹⁰ In time, as new food, cosmetic, personal care, or body care trends occur, or as new technology is used in product production, the certifications which the FDA provides can adapt and expand to fit consumers' desires for specific information.

This proposal gives food, cosmetic, body care, and personal care producers who are unable to meet the strict USDA organic regulation requirements an ability to honestly display what their product is made of, how it was made, or how the facilities in which it was made are operated. With uniform rules, the labeling goal of transparency is more likely to be met because consumers are able to quickly educate themselves on what a certain seal means in terms of certification qualifications.¹¹¹ The resulting clarity will allow consumers to make purchases based on what is most important or cost-effective to them.

B. A Definition for "Natural"

Since the main goal of labeling is informing consumers about what is in a product,¹¹² it is important that the words used on product labels accurately represent what consumers believe them to mean. Accordingly, when defining the term "natural" for use on product labels, the USDA needs to give great consideration as to what consumers currently understand the word to mean. According to the OTA, nearly three out of four consumers believe that "natural" food means that the ingredients in the product are grown without toxic pesticides, fertilizers, or GMOs.¹¹³ These requirements align much more closely with the standards for organic certification¹¹⁴ than they do with the FDA's brief list of the types of products that do not qualify as "natural."¹¹⁵

To best achieve the goals of labeling, the FDA should use the public comments from their previous request, along with new consumer studies about perceptions of what "natural" means, or should mean, in developing the definition for the word. As is done by the NOP for organic certification, lists of permitted and non-permitted ingredients should also be crafted to provide certainty to both producers and consumers. Producers should also be able to certify their products in a similar scheme to the NOP's four-levels of organic labeling—100% natural, 95% natural, partially natural, and contains natural [x]—in order to provide the clearest labels possible.¹¹⁶ Again, similar to the organic industry, in order to be able to use these

110. Wyard, *supra* note 74, at 13.

111. *Id.*

112. Bryne, *supra* note 10, at 35–36.

113. See Wyard, *supra* note 74, at 5–6.

114. See generally *Organic Certification and Accreditation*, *supra* note 48.

115. See generally "Natural" on Food Labeling, *supra* note 15. note 50 www.ams.usda.gov/organic/organic-certification/organic-labeling/organic-labeling-requirements/organic-labeling-requirements-101.aspx

116. See *Labeling Organic Products*, *supra* note 51.

words and seals on a label, a product should have to be approved by an FDA-certified agency.

C. A Requirement for Disclosure of Synthetically Derived Foods or Nutrients When Those Ingredients or Benefits Also Occur Naturally

In response to lawsuits such as *General Mills*,¹¹⁷ the FDA should mandate that if an ingredient or nutrient is being specifically promoted on the front of a product's package, and that ingredient or nutrient is generally believed to be naturally occurring, but is instead synthetically created, the front of the package must state that the ingredient or nutrient is not naturally derived. Requiring this will provide more accurate information to consumers who may otherwise unknowingly purchase a product with components which they were not aware could be made synthetically.

D. GMO Labeling

Since the 1990s, genetically engineered crops have become increasingly prevalent in the United States.¹¹⁸ As their presence continues to grow, it becomes difficult to produce products completely free of GMOs.¹¹⁹ As the above studies indicate however, roughly 70% of consumers believe that “natural” products do not contain GMOs.¹²⁰

There is no shortage of debates regarding whether or not a product containing GMOs should be considered “natural.”¹²¹ To alleviate misconceptions in the most practical way, the two words should be separated for the consumer in product labeling. In other words, the FDA should require that any product which is certified to use the words “natural,” “all natural,” or “100% natural” also include one of two secondary seals: “Contains GMOs” or “GMO-free.” This solution eliminates the need to come to a consensus regarding whether or not a naturally grown, genetically modified organism is “natural” or “unnatural.” Natural certification will not depend on GMO presence or lack thereof. In a sense, imposing a regulation of this type would create two new categories of products: Natural/GMO-free and Natural/GMO-present. This solution also allows manufacturers to more easily make changes to product labels reflecting ingredient changes, if need be, without having to greatly redesign the product packaging.

VI. CONCLUSION

Despite the fact that effective regulations exist for the use of the word “organic” on food products, insufficient standards are imposed for labeling non-food products as organic, or any product—food or non-food—as “natural.” Imposing regulations

117. See generally *Turek v. General Mills, Inc.*, 754 F. Supp. 2d 956, 957 (N.D. Ill. 2010).

118. Amaru, *supra* note 91, at 576.

119. See Liu, *supra* note 25, at 338.

120. Wyard, *supra* note 74 at 9.

121. Blau & Waingard, *supra* note 83; See generally *In re Conagra Foods, Inc.*, 90 F. Supp. 3d 919 (C.D. Cal. 2015); See generally *General Mills*, 754 F. Supp. 2d 956.

for using these words will help create a more transparent market and will eliminate deceit when consumers are choosing what products to put in their bodies and on their skin. Stating a definition for “natural” based on consumer perceptions, and creating a clear-cut, tiered labeling scheme—similar to that which is used to regulate the word “organic” on food products—will further the goals of labeling. Replacing private seals with government regulated ones will also help educate consumer about the contents of the product. Finally, imposing greater disclosure requirements—such as clearly stating if naturally occurring food is synthetically derived, or whether GMOs are present or not—is another way labeling goals can be met and misleading statements can be avoided. Along with more definitions, regulations, and requirements for disclosure, the integrity of the certifying bodies must be upheld to ensure these rules have meaning and consumers trust product certifications. The implementation of regulations similar to the ones this article has suggested will create more transparency between product packages and consumers of “organic” and “natural” food, cosmetic, and personal care items, and will eliminate deception and injustices that currently exist in these markets.