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## THE CASE AGAINST LACROIX: MOVING BEYOND THE INGREDIENT LIST IN “NATURAL” LITIGATION

*Christy Wyatt*

### I. INTRODUCTION

Consumers look to purchase foods labeled “natural” in the market. In 2013-2014, consumers spent over forty billion dollars purchasing foods labeled “natural.”<sup>1</sup> Additionally, 51% of consumers attempt to purchase only natural foods.<sup>2</sup> Despite these trends, the Food and Drug Administration (“FDA”) has yet to define or regulate the term “natural.”<sup>3</sup> Therefore, many consumers who desire to purchase foods that are labeled “natural” do not understand what the term means and do not think the term is trustworthy.<sup>4</sup> Many consumers equate the term “natural” with “organic” even though the standards are distinct.<sup>5</sup> This confusion has led both the food industry and consumers to request that the FDA define the term “natural.”<sup>6</sup> Additionally, the confusion surrounding the term “natural” has led to litigation.<sup>7</sup>

The amount of litigation surrounding the food industry has substantially increased over the past ten years.<sup>8</sup> Of the 158 class actions filed in 2018, thirty-three involved “all natural” labeling.<sup>9</sup> One of the trends in “natural” litigation is to argue over whether trace amounts of

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1. Nicole E. Negowetti, *Defining Natural Foods: The Search for a Natural Law*, 26 REGENT U.L. REV. 329, 329 (2014) (citing Mike Esterl, *The Natural Evolution of Food Labels*, WALL ST. J., Nov. 6, 2013, at B1).

2. *Id.* (citing Mike Esterl, *The Natural Evolution of Food Labels*, WALL ST. J., Nov. 6, 2013, at B1).

3. *Id.*

4. *Id.* (citing Mike Esterl, *The Natural Evolution of Food Labels*, WALL ST. J., Nov. 6, 2013, at B1) (stating that 47% of consumers don’t view the term “natural” as trustworthy).

5. *Id.* at 349 (quoting *Astiana v. Kashi Co.*, 291 F.R.D. 493, 508 (S.D. Cal. 2013); *Thurston v. Bear Naked, Inc.* No. 3:11-CV-02890-H(BGS), 2013 WL 5664985, at \*8 (S.D. Cal. July 30, 2013)). See also USDA, *Becoming a Certified Operation*, AGRIC. MARKETING SERVICE, <https://www.ams.usda.gov/services/organic-certification/becoming-certified> [<https://perma.cc/YVC5-LJZS>] (last visited October 22, 2019) (stating that to be organic the producer must fill out an application and have a USDA accredited certifying agency approve the application).

6. Negowetti, *supra* note 1, at 329 (citing Nicole E. Negowetti, *A National “Natural” Standard for Food Labeling*, 65 ME. L. REV. 581, 583 (2013)).

7. Regina L. Lamonica et al., *Food Litigation 2018 Year in Review: A look at Key Issues Facing our Industry*, PERKINS COIE, L.L.P., at 3-6 (Feb. 2019), <https://www.perkinscoie.com/images/content/2/1/v2/217858/2019-ALL-Food-Litigation-YIR-v2.pdf> [<https://perma.cc/V3CV-73CG>] (in 2008 there were 19 class actions filed against the food industry, in 2018 there were 158, the majority of which were filed in California and New York).

8. *Id.* at 3 (in 2008 there were 19 class actions filed against the food industry, in 2018 there were 158, the majority of which were filed in California and New York).

9. *Id.* at 3-6.

ingredients in the food make the food synthetic.<sup>10</sup> Scientific advances have allowed for trace amounts of ingredients to be detected more efficiently and at increasingly smaller levels.<sup>11</sup>

Part II of this Comment will give a brief history of the Food, Drug, and Cosmetic Act and the Federal Meat Inspection Act. Next, this Comment will describe how the FDA and the United States Department of Agriculture (“USDA”) regulate the terms “natural” and “natural flavor.” Part II will also discuss the facts surrounding *Rice v. National Beverage Corporation*<sup>12</sup> and *Graham v. National Beverage Corporation*.<sup>13</sup> Part III of this Comment will show how *Rice* and *Graham* highlight problems with current FDA and USDA regulations and policies regarding the term “natural.” Next, Part III will discuss the need for a unified definition for “natural” between the FDA and USDA. Finally, Part IV will offer suggestions on how the FDA and USDA could further regulate the terms “natural” and “natural flavor” to alleviate confusion and avoid future litigation.

## II. BACKGROUND

Part II will lay out the current United States regulatory landscape of the term of “natural.” Part II-A gives the history of the Food Drug and Cosmetic Act. Part II-B outlines the FDA’s policies and regulations on the term “natural” and “natural flavor.” Part II-C gives the history of the Federal Meat Inspection Act. Part II-D outlines the USDA’s policies and regulations regarding the terms “natural” and “natural flavor.” Part II-E will provide information on *Rice v. National Beverage Corporation*. Finally, Part II-F will describe *Graham v. National Beverage Corporation*.

### A. The Food Drug and Cosmetic Act

The Pure Food and Drugs Act, which was the first federal law that prohibited interstate commerce of misbranded and adulterated food, was

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10. *Id.* at 6 (this article specifically points out litigation of trace amounts of pesticides); *See, e.g.*, *Doss v. Gen. Mills, Inc.*, No. 18-61924-Civ-Scola, 2019 U.S. Dist. LEXIS 100791, at \*2 (S.D. Fla. June 14, 2019) (stating that glyphosate was found in a General Mills product ranging between 470 – 1,125 parts per billion).

11. *See* ANDREAS SCHIEBER, MODERN TECHNIQUES FOR FOOD AUTHENTICATION 7-8 (Da-Wen Sun ed., Academic Press 2d ed. 2018) (stating that between 2008 and 2018, 900 articles relating to methods of detecting and evaluating ingredients in food were published. These methods were either new techniques or modifying established techniques to evaluate a new food product. Examples include using gas chromatography to detect volatiles for raspberry flavor authentication (published in 2015) and using lactone analysis to determine the ripeness of pineapple (published in 2015)).

12. No. 18 CV 7151, 2019 U.S. Dist. LEXIS 114961 (N.D. Ill., July 11, 2019).

13. No. 19-CV-00873 (S.D. NY, filed Jan. 29, 2019).

enacted in 1906.<sup>14</sup> The Pure Food and Drugs Act was passed largely in response to Dr. Harvey Wiley’s experiments on the toxicity of food additives starting in 1902.<sup>15</sup> The group conducting these experiments was dubbed “the poison squad.”<sup>16</sup> The poison squad would eat increasingly high concentrations of common food additives to determine the additives’ effect on their health.<sup>17</sup> The first additive tested was borax.<sup>18</sup> Through the poison’s squad consumption of borax, borax was shown to cause headaches and stomach aches if consumed in large quantities.<sup>19</sup> Following borax, the poison squad tested other common additives used by food producers such as sulfuric acid, saltpeter, copper sulfate, and formaldehyde.<sup>20</sup> Some of these additives also caused health issues.<sup>21</sup> Given the results of his experiments, Dr. Wiley pressured Congress to pass a law regulating food additives.<sup>22</sup> Eventually, Dr. Wiley succeeded in doing so.<sup>23</sup>

By the 1930s, it was clear that the Pure Food and Drugs Act of 1906 was missing certain regulations to ensure food and drugs sold in the United States were safe.<sup>24</sup> After sitting in Congress for five years, the Food, Drug, and Cosmetic Act of 1938 was passed after a drug company legally marketed a drug containing antifreeze to pediatric patients that caused over one hundred deaths.<sup>25</sup> The purpose of the Food, Drug, and Cosmetic Act is to protect consumers from misbranded or adulterated food.<sup>26</sup> The Food, Drug, and Cosmetic Act allows the FDA to “promulgate food definitions and standards of food quality; set tolerance levels for poisonous substances in food; and take enforcement action on

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14. *Milestones in U.S. Food and Drug Law History*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/about-fda/fdas-evolving-regulatory-powers/milestones-us-food-and-drug-law-history> [<https://perma.cc/6BJN-K2BY>] (last visited on Sept. 27, 2019).

15. Bruce Watson, *The Poison Squad: An Incredible History*, ESQUIRE (June 27, 2013), <https://www.esquire.com/food-drink/food/a23169/poison-squad/> [<https://perma.cc/8TR6-88W9>].

16. *Id.*

17. *Id.*

18. *Id.*

19. *Id.*

20. *Id.*

21. *Id.* (Copper sulfate “caused a host of health woes including nausea, diarrhea, vomiting, liver damage, kidney damage, brain damage, and jaundice”).

22. *Id.*

23. *Milestones in U.S. Food and Drug Law History*, *supra* note 14.

24. *Part II: 1938, Food, Drug, Cosmetic Act*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/about-fda/fdas-evolving-regulatory-powers/part-ii-1938-food-drug-cosmetic-act> [<https://perma.cc/4HQJ-NXEG>] (last updated Nov. 27, 2018) (For example, it wasn’t clear how the FDA was able to conduct factory inspections and did not have enough control over how companies could advertise and market their products).

25. *Id.*

26. *United States v. Bradshaw*, 840 F.2d 871, 874 (11th Cir. 1988).

adulterated and misbranded foods.”<sup>27</sup> Under the Food, Drug, and Cosmetic Act, a food is misbranded if “its labeling is false or misleading in any particular.”<sup>28</sup> For example, when a food product incorrectly states that it is all “natural,” it is considered misleading and is therefore misbranded under the Food Drug and Cosmetic Act.<sup>29</sup>

### *B. Food and Drug Administration on “Natural” and “Natural Flavors”*

The FDA regulates all food products except for some meat, poultry, and processed egg products.<sup>30</sup> This equates to “about 77% of the U.S. food supply.”<sup>31</sup> Even though the FDA admits that regulating the term “natural” could alleviate consumers’ and food manufacturers’ confusion, it has declined to provide an enforceable definition.<sup>32</sup> However, the FDA has a policy stating that the term “natural” means “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.”<sup>33</sup> In 2012, the FDA gave its reason for declining to define the term “natural” as:

From a food science perspective, it is difficult to define a food product that is “natural” because the food has probably been processed and is no longer the product of the earth. That said, the FDA has not developed a definition for the use of the term natural or its derivatives. However, the agency has not objected to the use of the term if the food does not contain added color, artificial flavors, or synthetic substances.<sup>34</sup>

Additionally, the FDA has considered regulating the term “natural” in the past, and asked for comments from the public on what they believed

27. *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 331 (3d Cir. 2009) (quoting *Fellner v. Tri-Union Seafoods, L.L.C.*, 539 F.3d 237, 251 (3d Cir. 2008)).

28. 21 U.S.C. § 343 (2019).

29. *See Holk*, 575 F.3d at 332 (plaintiff filed a claim stating that the all natural claim on Snapple teas was misleading because there was high fructose corn syrup in it.); *See also Viggiano v. Hansen Natural Corp.*, 944 F. Supp. 2d 877, 881-82 (C.D. Cal. 2013) (plaintiff stating that defendant’s soda can label stating “all natural flavors” was misleading because the soda contained artificial substances).

30. *Regulated Products*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/industry/import-basics/regulated-products> [<https://perma.cc/3VPL-G79C>] (last updated Jan. 7, 2020).

31. *Fact Sheet: FDA at a Glance*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance> [<https://perma.cc/55X7-P72Y>] (last updated Oct. 18, 2019).

32. Negowetti, *supra* note 1, at 330.

33. *Use of the Term Natural on Food Labeling*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/food/food-labeling-nutrition/use-term-natural-food-labeling> [<https://perma.cc/RJ4D-CG97>] (last updated Oct. 22, 2018).

34. Negowetti, *supra* note 1, at 332. (quoting *About FDA, What Is the Meaning of ‘Natural’ on the Label of Food?*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm214868.htm> (last updated Apr. 4, 2012)).

“natural” should mean in 2016.<sup>35</sup>

As a result of the FDA’s refusal to provide an enforceable definition of “natural,” Congress attempted to pass the Food Labeling and Modernization Act, which would define “natural.”<sup>36</sup> Congress took up the Food Labeling and Modernization Act because it feared that the public was losing confidence in food labels.<sup>37</sup> According to the proposed Food Labeling and Modernization Act, if a food product contains any artificial ingredients, including flavors or colors that were not naturally occurring, the food could not be labeled “natural.”<sup>38</sup> However, Congress has thus far failed to pass the Food Labeling and Modernization Act of 2013.<sup>39</sup>

Even though the FDA (and Congress) have either failed or chosen to not to define the term “natural,” the FDA has created an enforceable definition for the term “natural flavor.”<sup>40</sup> According to the FDA, the term “natural flavor” means:

The essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional.<sup>41</sup>

Besides being able to claim that all flavors are “natural” on the package, “natural flavor” can be used as an ingredient on the ingredient list instead of listing out all the specific flavoring ingredients.<sup>42</sup>

Another aspect of labelling that could potentially affect whether a food product could be considered natural are incidental additives.<sup>43</sup> An incidental additive is either: (1) a functional ingredient in an ingredient present in the finished product, but is in the finished product at an insignificant amount and has no function in the finished product; or (2) an ingredient that was used in the processing of a food product, but no

35. *Use of the Term Natural on Food Labeling*, *supra* note 33.

36. Amy-Lee Goodman, Note, *A “Natural” Stand Off Between the Food and Drug Administration and the Courts: The Rise in Foodlabeling Litigation & The Need for Regulatory Reform*, 60 B.C.L. REV. 271, 305 (2019) (citing H.R. 3147, 113th Cong. § 4(aa) (2013)).

37. *Id.* (citing Bruce Silverglad & Ilene Ringel Heller, Ctr. For Sci. Pub. Int., *Rebuttal to FDA Report to Congress on Agency Enforcement Actions Regarding Health Related Claims on Food Labels 1* (2006)). <https://cspinet.org/sites/default/files/attachment/fn5rep.pdf>.

38. *Id.* (citing H.R. 3147, 113th Cong. § 4(aa) (2013)).

39. *Id.* (citing H.R. 5425, 115th Cong. (as proposed on Apr. 2, 2018) (introducing a variation of the Food Labeling and Modernization Act)).

40. *See* 21 C.F.R. § 101.22 (2019).

41. 21 C.F.R. § 101.22(a)(3) (2019).

42. 21 C.F.R. § 101.22(h)(1) (2019).

43. *See* 21 C.F.R. § 101.22(h)(2) (2019); *See also* 21 C.F.R. § 101.100(a)(3) (2019).

longer has a function in the finished product.<sup>44</sup> An example of an incidental additive would be if natural flavoring ingredients were mixed with propylene glycol (a synthetically made solvent). The flavor, which includes the propylene glycol, is put into a finished product, yogurt for example, at 0.2 percent. The propylene glycol is in the yogurt at such a low level that it is no longer functional. Therefore, it would be considered an incidental additive and would not be labeled. The fact that propylene glycol is not labeled does not affect whether the flavor is considered natural. Therefore, the flavor on the ingredient list would be labeled “natural flavor.”<sup>45</sup>

### C. The Federal Meat Inspection Act

In response to Upton Sinclair’s 1906 novel, *The Jungle*, which detailed the unsanitary conditions of the meat packing industry, Congress passed The Federal Meat Inspection Act, one of the first laws regulating the meat industry.<sup>46</sup> The Federal Meat Inspection Act gave the USDA authority to inspect meat products, and prohibited the sale of adulterated or misbranded meat.<sup>47</sup> The Food Safety and Inspection Service (“FSIS”) is the branch of the USDA that inspects meat products and adulterated food.<sup>48</sup> Throughout the next seventy years, Congress gave the USDA the right to inspect and regulate poultry and egg products.<sup>49</sup> In passing the Federal Meat Inspection Act Congress stated that it is “essential [to] the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged.”<sup>50</sup> Under the Federal Meat Inspection Act, a food is “misbranded” if “its labeling is false or misleading in any particular,”<sup>51</sup> or “[i]f it bears or contains any . . . chemical preservative[s], unless it

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44. 21 C.F.R. § 101.100(a)(3)

45. See 21 C.F.R. § 101.22(h)

46. *Celebrating 100 years of FMIA*, USDA FOOD SAFETY & INSPECTION SERVICE, [https://www.fsis.usda.gov/wps/wcm/connect/fsis-content/fsis-questionable-content/celebrating-100-years-of-fmia/overview/ct\\_index](https://www.fsis.usda.gov/wps/wcm/connect/fsis-content/fsis-questionable-content/celebrating-100-years-of-fmia/overview/ct_index) [<https://perma.cc/J3NZ-JPHU>] (last updated Feb. 21, 2014).

47. *FSIS History*, USDA FOOD SAFETY & INSPECTION SERVICE, <https://www.fsis.usda.gov/wps/portal/informational/aboutfsis/history> [<https://perma.cc/UD75-CVTP>] (last updated Feb. 21, 2018).

48. *Federal Food Safety Laws*, NAT’L CONF. OF ST. LEGISLATURES (Nov. 6, 2009), <http://www.ncsl.org/research/agriculture-and-rural-development/federal-food-safety-laws.aspx> [<https://perma.cc/BT34-UER6>].

49. *Celebrating 100 years of FMIA*, *supra* note 46.

50. *Hormel Foods Corp. v. U.S. Dep’t of Agric.*, 808 F. Supp. 2d 234, 236 (D.D.C. 2011). (citing 21 U.S.C. § 602 (2006)).

51. *Id.* at 237 (citing 21 U.S.C. § 610(n)(1) (2006)).

bears a label stating that fact.”<sup>52</sup> The only exception is if the Secretary of Agriculture has exempted a specific chemical preservative from being labeled.<sup>53</sup> Congress has extended the same definitions to poultry regulations.<sup>54</sup>

*D. United States Department of Agriculture on “Natural” and “Natural Flavors”*

The USDA regulates meat, poultry, products containing meat and poultry, processed egg products, and catfish.<sup>55</sup> Additionally, the USDA oversees the National Organic Program and regulates the use of the term “organic.”<sup>56</sup>

Like the FDA, the USDA does not have a regulated definition of the term “natural.”<sup>57</sup> However, in 1982 the FSIS implemented a policy regarding the use of the term “natural” on meat products.<sup>58</sup> This policy is one of the more well defined versions of “natural” within the United States.<sup>59</sup> If a product does not contain any “ [1] artificial flavor or flavoring, coloring ingredient, chemical preservatives (as defined by 21 CFR [§] 101.22), or any other artificial or synthetic ingredient; and (2) the product and its ingredients are not more than minimally processed,” the product can be labeled “natural.”<sup>60</sup> “Minimally processed” includes traditional preparation methods of food, such as freezing or smoking, or processes where the raw food is not “fundamentally altered,” such as grinding or pressing.<sup>61</sup> The policy guidelines also state that whether foods containing “natural flavors” under 21 CFR § 101.22 are considered “natural” will be determined on a case by case basis because “natural flavors” are typically more than “minimally processed.”<sup>62</sup> The USDA

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52. *Id.* (citing 21 U.S.C. § 610(n)(11) (2006)).

53. *Id.* (citing 21 U.S.C. § 610(n)(11) (2006)).

54. *See id.* (citing 21 U.S.C. §§ 452, 458, 453).

55. *Principal Food Safety Regulatory Organizations: FDA vs USDA-FSIS*, NC ST., <https://ncfsma.ces.ncsu.edu/wp-content/uploads/2018/01/FDA-versus-USDA.pdf?fwid=no> [<https://perma.cc/KVQ9-CW37>] (last accessed Sept. 28, 2019).

56. *Organic on Food Labels*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/food/food-labeling-nutrition/organic-food-labels> [<https://perma.cc/GGQ5-ZTJM>] (last updated Dec. 27, 2017).

57. *See* Matthew J. Goodman, *The “Natural” vs. “Natural Flavors” Conflict in Food Labeling: A Regulatory Viewpoint*, 72 FOOD & DRUG L.J. 78, 86 (2017) (citing Nicole E. Negowetti, *A National Natural Standard for Food Labeling*, 65 ME. L. REV. 581, 589 - 90 (2013)).

58. *See id.* (citing Allyson Weaver, *Natural Foods: Inherently Confusing*, 39 J. CORP. L. 657, 664 (2014)).

59. *See* FOOD SAFETY & INSPECTION SERV., FOOD STANDARDS AND LABELING POLICY BOOK 109 (2005), available at <https://www.fsis.usda.gov/wps/wcm/connect/7c48be3e-e516-4ccf-a2d5-b95a128f04ae/Labeling-Policy-Book.pdf?MOD=AJPERES> [<https://perma.cc/3ASX-9JXJ>].

60. *Id.*

61. *Id.*

62. *Id.* (stating that a product containing a natural flavor that was more than minimally processed

must approve all product labels before use by food companies, while the FDA does not approve product labels before use.<sup>63</sup>

The USDA has also determined what is considered “natural” specific to the context of certified organic products.<sup>64</sup> “Natural,” used interchangeably with the term “nonsynthetic,” is defined as “a substance that is derived from mineral, plant, or animal matter and does not undergo a synthetic process as defined in [§] 6502(21) of the Act (7 U.S.C. [§] 6502(21)).”<sup>65</sup> Even though this definition only applies to organic products, it has been used in cases determining the appropriateness of a “natural” label outside of the organic context.<sup>66</sup> In regards to flavors, a flavor that cannot be certified organic can be added to an organic product if all flavors are “derived from organic or nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems.”<sup>67</sup> Therefore, the definition of flavors allowed in organic products is much stricter than in 21 CFR § 101.22, where flavors can still be labeled “natural” while using synthetic incidental additives and carriers.

### *E. Rice v. National Beverage Corporation*

On October 25, 2018, plaintiff Lenora Rice (“Rice”) filed a class action stating that LaCroix Sparkling Waters (“LaCroix”), owned by National Beverage Corporation, contained synthetic flavoring ingredients even though LaCroix stated that their sparkling water was “all natural” on both their website and on their boxes.<sup>68</sup> Rice was a consumer of LaCroix who claimed she would not have purchased LaCroix had she known that it

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may still be allowed to have a natural label if it can be proved that the natural flavor does not “significantly change the character of the product to the point it would no longer be considered a natural product.” However, the kinds of natural labeling that can be used may be limited. For example, a product may be allowed to be labeled “natural,” but not “all natural.”

63. See Food Safety & Inspection Serv., *Labeling*, USDA FOOD SAFETY & INSPECTION SERVICE, <https://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/siluriformes/labeling> [<https://perma.cc/KJT3-YBVB>] (last updated Jan. 5, 2018); See also FDA, GUIDANCE FOR INDUSTRY: A FOOD LABELING GUIDE 4 (2013), available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-labeling-guide> [<https://perma.cc/YUK5-UMAZ>] (stating the FDA does not require pre-approval).

64. See 7 C.F.R. § 205.2 (2019).

65. *Id.*

66. See *Rice v. Nat'l Beverage Corp.*, No. 18 CV7151, 2019 U.S. Dist. LEXIS 114961, at \*13-14 (N.D. Ill., July 11, 2019) (stating that the plaintiff argued flavors in LaCroix are synthetic according to the definition in 7 C.F.R. § 205.2).

67. 7 C.F.R. § 205.605 (2019).

68. Class Action Complaint at 3-4, *Rice*, 2019 U.S. Dist. LEXIS 114961 (No. 2018CH12302) (Stating that LaCroix contains ethyl butanoate, limonene, linalool, and linalool propionate which are all synthetically created. Additionally, plaintiff states that these chemicals will have negative affects to health. For example, limonene can cause kidney toxicity and tumors).

contained synthetic ingredients.<sup>69</sup> Rice claimed LaCroix knew that synthetic chemicals were in their flavoring and is misleading consumers by stating their products are “all natural.”<sup>70</sup> Rice alleged three causes of action: violation of express warranties, unjust enrichment, and violation of the Illinois Consumer Fraud Act.<sup>71</sup>

In its answer, LaCroix stated that the alleged synthetic ingredients are flavoring compounds that are available both synthetically and naturally.<sup>72</sup> LaCroix further asserted that they require certification from their suppliers proving all of their ingredients are natural, and have all of their products tested by an accredited third party laboratory to ensure that all of their products are completely natural.<sup>73</sup> Finally, LaCroix stated that Rice did not show any proof that they tested LaCroix’s sparkling water in a way that could determine whether ingredients in the sparkling water were artificially or naturally derived.<sup>74</sup> Therefore, LaCroix moved to dismiss the complaint.<sup>75</sup>

LaCroix also filed a motion for sanctions against Rice, stating that Rice brought the lawsuit recklessly and in bad faith.<sup>76</sup> LaCroix claimed that the testing method Rice used to determine whether there were synthetic chemicals in the sparkling water would only be successful in determining whether an ingredient was in LaCroix, not if the ingredient was natural or synthetic.<sup>77</sup> Additionally, LaCroix pointed out that the test Rice performed on the sparkling water was intended to identify different compounds than the compounds that Rice claimed were synthetic in the complaint.<sup>78</sup> LaCroix stated that since Rice’s testing was not meant to identify the compounds included in the complaint, Rice’s testing was inadequate.<sup>79</sup>

Additionally, LaCroix claimed the regulation that Rice used to “prove”

69. *Id.* at 5.

70. *Id.* at 4.

71. *Id.* at 8-9.

72. Answer and Affirmative Defenses to Class Action Complaint at 4-7, *Rice*, 2019 U.S. Dist. LEXIS 114961 (No. 1:18-cv-07151) (Specifically, the substances that the plaintiff lists in the complaint “naturally occur in fruits and plants such as strawberries, pineapples, oranges, apples, limes, apricots, bananas, plums, tangerines, blueberries, sage, lavender).

73. *Id.* at 3-4.

74. *Id.* at 2.

75. *Id.* at 17.

76. Nat’l Beverage Corp.’s Reply in Support of Motion for Sanctions pursuant to Federal Rule of Civil Procedure 11 at 2 -4, *Rice*, 2019 U.S. Dist. LEXIS 114961 (No. 1:18-cv-7151) (claims that plaintiff misinterpreted 21 C.F.R. § 182.60 when arguing that the flavors listed in that section are synthetic *per se.*).

77. *Id.*

78. *Id.* at 17 (stating that the test plaintiff ran was to identify whether glycerin, propylene glycol, ascorbic acid, erythritol, or ethanol was present. The synthetic compounds the plaintiff claims are in LaCroix are ethyl butanoate, limonene, linalool, or linalool propionate).

79. *Id.*

that the flavoring compounds found in the sparkling water were synthetic did not state that the flavoring compounds in the sparkling water must be synthetic if they are found in food products; the regulation only stated that the compounds are allowed to be used in food products if they are produced synthetically.<sup>80</sup> To further its point that the compounds involved in this suit can be naturally derived, LaCroix gave examples of natural sources of these flavoring compounds.<sup>81</sup>

The court refused to grant LaCroix's motion for sanctions.<sup>82</sup> The court stated that there was nothing "obviously misguided and unreasonable" about how Rice interpreted the relevant regulations.<sup>83</sup> Additionally, the court stated that because the FDA has not specifically ruled on whether the flavoring compounds in LaCroix's water are natural or synthetic, whether these compounds are "natural" is debatable.<sup>84</sup> Therefore, the court reasoned it should not decide at this stage whether the flavoring ingredients in the sparkling water were natural.<sup>85</sup>

#### F. *Graham v. National Beverage Corporation*

A second class action, *Graham v. National Beverage Corporation*, was filed against LaCroix on January 29, 2019 alleging that the flavors in their sparkling waters contained synthetic ingredients.<sup>86</sup> The claims against LaCroix in *Graham* were similar to those in *Rice*.<sup>87</sup> In *Graham*, the claims included unjust enrichment, violations of the Unfair and Deceptive Trade Practices Act of New York, violations of the New York Deceptive Sales Practices Act, and breach of contract and warranty.<sup>88</sup> However, the complaint more fully discussed the testing the plaintiffs used to determine that there are synthetic ingredients in LaCroix sparkling waters.<sup>89</sup> The

80. *Id.* at 4 (citing 21 C.F.R. § 182.60 (provides a list of chemicals that can be used in food products even if they are made synthetically)).

81. *Id.* at 20 (for example limonene naturally occurs in lemon).

82. *Rice*, 2019 U.S. Dist. LEXIS 114961, at \*21.

83. *Id.* at \*11.

84. *Id.* at \*15-16.

85. *Id.* at \*16.

86. Class Action Complaint at 1-2, *Graham v. Nat'l Beverage Corp.*, No. 19-cv-00873 (S.D.N.Y. Jan. 29, 2019).

87. *See id.* at 22-29; *See also* Class Action Complaint, *supra* note 68, at 8-9.

88. Class Action Complaint, *supra* note 86, at 22-29.

89. *See id.* at 14-15. (Using results from University of Georgia Center for Applied Isotope Studies); *See Food, Flavor & Beverage Authenticity Testing*, U. GA. CENTER FOR APPLIED ISOTOPE STUD., <https://cais.uga.edu/service/food-flavor-and-beverage-authenticity-testing/> [https://perma.cc/73P8-AF5Q] (last visited Sept. 27, 2019) (stating that the naturalness of a food product can be determined by testing to see if compounds in fossil fuels are in the product using a GC/IRMS); *See also Gas Chromatography Combustion Isotope Ratio Mass Spectrometry (GC/IRMS)*, U. BRISTOL, <http://www.bris.ac.uk/nerclsmf/techniques/gccirms.html> [https://perma.cc/2SNV-9J2P] (last updated Jan. 14, 2008) (stating that GC/IRMS allows testers to identify specific molecules in a product by putting

complaint claimed that the 36-98% of the ingredients in the LaCroix's flavors were synthetic.<sup>90</sup>

LaCroix defended itself by arguing that it has superior knowledge of its products and has had them tested by an accredited third party to prove that they are "all natural."<sup>91</sup> LaCroix also stated that Graham failed to state which specific flavoring compounds are synthetic.<sup>92</sup> Currently, there is no information on whether the synthetic compounds detected by Graham were from flavoring ingredients themselves or incidental additives that are no longer functional in LaCroix sparkling water.<sup>93</sup>

After this comment was written, both *Rice* and *Graham* were dismissed.<sup>94</sup> However, their dismissals do not affect either the analysis of this comment or the need for the FDA and USDA to create a uniform definition of the term "natural."

### III. ANALYSIS

Part A of this section analyzes the problems in "natural" litigation that are emphasized by *Rice* and *Graham*. Part B explains the confusion that the different regulations and policies regarding the use of the term "natural" creates, showing the need for a unified definition of the term "natural" between the FDA and USDA. Finally, Part C provides potential solutions that the FDA and USDA can implement to avoid "natural" litigation.

#### *A. Rice and Graham Emphasize Problems in "Natural" Litigation*

*Rice* and *Graham* demonstrate some of the problems that occur when the FDA and USDA do not have a unified regulation on what "natural" means. The FDA and USDA's conflicting definitions result in unnecessary litigation over the meaning of "natural." These problems are emphasized when the ingredients in question are in the product in small amounts and not on the ingredient statement.

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compound through a column which will separate the molecules depending on how the molecule reacts with the material the column is made out of as well as the gas carrying the compound through the column).

90. Class Action Complaint, *supra* note 86, at 15.

91. Defendant Nat'l Beverage Corp.'s Answer and Affirmative Defenses to Class Action Complaint at 2, 13-14, *Graham v. Nat'l Beverage Corp.*, No. 19-cv-00873 (S.D.N.Y. Feb. 25, 2019).

92. *Id.* at 30.

93. Elaine Watson, *LaCroix Maker Slams 'Professional Liars' behind New Lawsuit Challenging its All-Natural Credentials*, FOODNAVIGATOR (Feb. 4, 2019) <https://www.foodnavigator-usa.com/Article/2019/02/04/LaCroix-maker-slams-professional-liars-behind-new-lawsuit-challenging-its-all-natural-credentials> [<https://perma.cc/QB3F-PF4T>].

<sup>94</sup>Order of Dismissal, *Graham v. Nat'l Beverage Corp.*, No. 19-cv-00873 (S.D.N.Y. Sept. 15, 2020); Order of Dismissal, *Rice v. Nat'l Beverage Corp.*, No. 1:18-cv-07151 (N.D. Ill. Feb. 18, 2020).

*i. Rice and Graham Forces Courts to Decide which Party's Testing is Accurate*

One of LaCroix's main defenses is that its own testing of its sparkling water is better than the Rice's and Graham's testing.<sup>95</sup> This argument is a more technical argument than is used in other cases involving the definition of "natural," where the parties argue whether an ingredient listed on an ingredient statement or a type of ingredient can be included in a "natural" product.<sup>96</sup> Cases determining whether a labeled ingredient can be present in a food that is labeled "natural" are easier to decide because the parties both agree that the ingredient is in the food product and how the product is processed. The parties only disagree about whether the ingredient can be in a "natural" product. Therefore, the courts are only required to determine whether they believe that specific ingredients can be present in a natural product.

Determining whether an ingredient can be in a product and the product can still be called "natural" is very different than *Rice* and *Graham*, where the court must determine which party's testing is more accurate. Courts may have difficulty determining which party's test is more accurate because of the scientific knowledge needed to distinguish between different types of tests. An expert witness may be necessary to evaluate the testing methods. Additionally, multiple testing methods could be accredited, but have different results. For example, in *Graham*, both parties use testing methods that are accredited by the International Organization for Standardization,<sup>97</sup> but these tests came to different conclusions regarding whether the ingredients in question are "natural." Therefore, it will be extremely difficult for courts to determine which accredited testing method is accurate. Evaluating these different accredited tests could be too technical a question for courts to consistently

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95. See Defendant Nat'l Beverage Corp.'s Answer and Affirmative Defenses to Class Action Complaint, *supra* note 91, at 13-14; See also Answer and Affirmative Defenses to Class Action Complaint, *supra* note 72, at 3-4.

96. See, e.g., *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) (determining whether a product could be all natural when it contained labeled alkalized cocoa powder); See also *In re Frito-Lay N. Am., Inc.*, No. 12-MD-2413 (RRM)(RLM), 2013 U.S. Dist. LEXIS 123824, at \*4 (E.D.N.Y. Aug. 29, 2013) (determining whether products containing genetically modified ingredients could be labeled as "all natural."); See also *Larsen v. Trader Joe's Co.*, 917 F. Supp. 2d 1019, 1021 (N.D. Cal. 2013) (determining whether ascorbic acid could be present in a product with an "all natural" label).

97. See *Food, Flavor & Beverage Authenticity Testing Facility*, U.GA. CENTER FOR APPLIED ISOTOPE STUD., <https://cais.uga.edu/facilities/food-flavor-and-beverage-authenticity-testing-facility/> [<https://perma.cc/7BSZ-ZKR7>] (last visited Oct. 20, 2019) (University of Georgia's testing to determine synthetic ingredients in food is accredited under the ISO/IEC 17025:2005 standards. This is the test that plaintiffs in *Graham* used.); See also Defendant Nat'l Beverage Corp.'s Answer and Affirmative Defenses to Class Action Complaint, *supra* note 91, at 4 (stating that LaCroix tests its product using an independent third party laboratory that is also accredited by ISO).

determine. For example, it would be possible for the court in *Rice* to determine that LaCroix's testing is more accurate and LaCroix could be labeled "all natural." However, the court in *Graham* could determine that the plaintiff's testing was more accurate and LaCroix would either need to change their formula or remove the "all natural" claim on their label. This outcome would be extremely problematic for LaCroix as they would be able to label their product as "all natural" in some jurisdictions, but not others. LaCroix would be forced to either remove the "all natural" claim from all their containers, most likely harming their brand,<sup>98</sup> or make two separate labels and track exactly where each label can be sold.

*ii. Graham and Rice Demonstrate Problems that Arise when the FDA and USDA do not Define Whether Synthetic Incidental Additives can be Included in "Natural" Products*

*Graham* and *Rice* demonstrate the problems that arise when the FDA and USDA do not provide quantitative limits for when an ingredient can be in a food product without affecting whether the product is "natural." The amount of liquid flavoring in most beverages is less than one percent. Therefore, even though *Graham* claims that the flavors in LaCroix contained 36% - 98% of synthetic ingredients<sup>99</sup>, the amount of synthetic ingredients in the total product is a very small percentage of the entire beverage. When the percentage of synthetic ingredients is low, it may be difficult to determine whether the synthetic ingredient is part of a flavoring compound, or if it is an incidental additive. In *Graham*, the complaint does not allege specific synthetic compounds present in LaCroix's sparkling water, making it difficult for LaCroix to defend themselves.<sup>100</sup> Because the FDA has no policy on how to handle litigation around the use of "natural" when the synthetic compound is an incidental additive, the courts are left to determine if synthetic compounds that are incidental additives affect whether a product can be labeled "natural." Additionally, courts must determine what levels of incidental additives must be present in the food product before the product can no longer be labeled "natural." Leaving it up to the courts to determine what effect incidental additives have on "natural" labeling, could result in jurisdictional splits which make it challenging for companies to properly label their products.

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98. See Nat'l Beverage Corp.'s Motion for Fees and Sanctions Pursuant to Federal Rule of Civil Procedure 11, *supra* note 76, at 1 (stating that LaCroix has developed a "spectacular, great-tasting, healthy product" that "America became 'enamored' with").

99. Class Action Complaint, *supra* note 86, at 2.

100. See Defendant Nat'l Beverage Corp.'s Answer and Affirmative Defenses to Class Action Complaint, *supra* note 91, at 30.

*iii. Rice and Graham Demonstrate how Parties can Manipulate Current “Natural” Regulations to Benefit Themselves*

In *Rice* and *Graham*, both parties try to manipulate regulations in a way that benefits themselves, but that is not directly applicable to the case at hand. For example, Rice uses the organic definition of “natural flavor” to try to prove that LaCroix Sparkling Water is not “natural.”<sup>101</sup> While this information may be influential in a court, LaCroix Sparkling Water is not certified organic.<sup>102</sup> Therefore, in *Rice*, the organic regulations are not binding. Rice also tried to use FSIS’s definition of “natural.”<sup>103</sup> However, LaCroix’s sparkling water is regulated by the FDA, not the USDA.<sup>104</sup> Again, the plaintiff’s use of FSIS guidelines might be persuasive, but is not binding in this case.

Unlike Rice, LaCroix uses the FDA definition of “natural flavor” to prove that their sparkling water meets the requirements to label their product “natural.”<sup>105</sup> While this definition comes from the proper regulatory agency, the definition of “natural flavor” does not apply to entire food products because there are other ingredients besides flavoring compounds in finished products. Additionally, incidental additives are not considered when determining whether a flavor is “natural” because incidental additives are not considered flavoring ingredients.<sup>106</sup> Similar to the arguments made by Rice, using the definition of “natural flavor” may be influential, but it is not binding in determining whether an entire product can be labeled “natural.” Without a clear standard to use, the courts will have to either try to use the regulation that aligns the closest with the issue at hand, develop their own standard for whether the entire product is “natural,” or stay litigation pending an FDA definition of “natural.”<sup>107</sup>

The issues presented in *Rice* and *Graham* show the need for the FDA to give a clear standard on the definition of a “natural” product and whether incidental additives affect whether a product is “natural.”

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101. *Rice v. Nat’l Beverage Corp.*, 18 CV 7151, 2019 U.S. Dist. LEXIS 114961, at \*21 (N.D. Ill., July 11, 2019).

102. See Class Action Complaint, *supra* note 86, at 7-13 (if LaCroix was organic, it would have an organic seal on the cans and box).

103. *Rice*, 2019 U.S. Dist. LEXIS 114961, at \*14.

104. *Principal Food Safety Regulatory Organizations: FDA vs USDA-FSIS*, *supra* note 55.

105. *Rice*, 2019 U.S. Dist. LEXIS 114961, at \*14-15.

106. See 21 C.F.R. § 101.22(h) (2019).

107. See Goodman, *supra* note 36, at 309-11 (stating that there is tension between the courts and the FDA defining the term natural, and that the courts should stay litigation).

*B. Comparison of the Different Government Regulations and the Need for a Standardized Definition between the FDA and the USDA.*

The current FDA policy on the use of the term “natural” is lacking and leaves the courts to determine whether a given product is “natural” without much help. The FDA states that the product cannot contain any synthetic ingredients.<sup>108</sup> However, the FDA does not provide any clarity on the definition of a synthetic ingredient. Additionally, this definition does not address whether incidental additives would be considered synthetic ingredients, or if the synthetic ingredients within the meaning of the regulation are only ingredients that must be labeled. If incidental additives are included within synthetic ingredients not allowed in “natural” products, then the FDA lacks a policy defining at what levels incidental additives need to be present in a food product before it affects the “natural” status of food. Determining the level of incidental additives is important because there will almost always be residual amounts of synthetic compounds in food products, which could lead to litigation.<sup>109</sup>

When compared to the FDA’s definition of “natural flavor,”<sup>110</sup> the FDA’s guidance on “natural” becomes even more problematic and confusing. “Natural flavors” specifically exclude incidental additives when determining whether a flavor is considered “natural.”<sup>111</sup> If the FDA guidelines interpret incidental additives as determinative of whether a product is “natural,” then a “natural flavor” with a synthetic incidental additive could be added to an otherwise natural product and prevent the product from being labeled “natural.”<sup>112</sup> This has the potential to confuse the industry. For example, assume that a manufacturer making yogurt adds “natural flavor” into their yogurt. Everything in the yogurt is natural, but the “natural flavor” contains incidental additives. The incidental additives are not labeled when the flavor manufacturer sends the flavor to the yogurt manufacturer. Because the flavor is labeled “natural flavor” and the synthetic incidental additives are not labeled, the yogurt manufacturer has no reason to know that there are synthetic ingredients in the yogurt and can no longer call the yogurt “natural.” This example demonstrates the need for the FDA to clarify whether incidental additives

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108. Negowetti, *supra* note 1, at 332 (quoting *About FDA, What Is the Meaning of ‘Natural’ on the Label of Food?* FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm214868.htm> (last updated Apr. 4, 2012)).

109. *See, e.g., In Re Gen. Mills Glyphosate Litig.*, No. 16-2869 (MJD/BRT), 2017 U.S. Dist. LEXIS 108469, at \*2-3 (D. Minn. July 12, 2017) (case involving whether the claim “made with 100% Natural Whole Grain Oats” is misleading when there are trace amounts of glyphosate found in the oats (0.45 parts per million)).

110. 21 C.F.R. § 101.22(a)(3) (2019).

111. *See* 21 C.F.R. § 101.22(h) (2019).

112. *See* Goodman, *supra* note 57, at 97.

affect the product's status as "natural." If the incidental additives are determinative of whether a product is "natural," the FDA most likely will have to change the definition of "natural flavor" to more closely align with their policy to avoid confusion like in the example above.<sup>113</sup>

The FSIS's policy is clearer than the FDA's about what is considered "natural" because it includes that "natural" products cannot be more than minimally processed.<sup>114</sup> Additionally, FSIS's policy is narrower than the FDA's policy because FSIS does not allow "natural" products to be more than minimally processed or to contain ingredients that have been more than minimally processed. The FDA does not have any policy on how heavily processed a "natural" product can be.<sup>115</sup> The FSIS also addresses whether "natural flavors" will be allowed in products regulated by the USDA.<sup>116</sup> While the FSIS's policy may be easier to follow, it would likely severely limit the number of "natural flavors" that would be allowed in "natural" products.<sup>117</sup> Additionally, adding a "natural" product regulated by the FDA to a product regulated by the USDA may prevent the USDA product from being able to be labeled as "natural." For example, if a meat packer wanted to add a "natural flavor" to their meat, adding the flavor could cause the meat product to no longer meet the definition of "natural" if the flavor was more than minimally processed.

While organic regulations may be helpful in determining what is "natural," organic certification is a separate and more stringent procedure.<sup>118</sup> Therefore, it is easier to keep organic "natural" definitions separate from other policies and regulations regarding the term "natural." However, even though it is easier to separate out the USDA's definition of "natural" in organic products, the different standards for "natural flavor" in organic products can confuse consumers. The USDA's definition of "natural flavor" in their organic regulations is much more stringent than the FDA's definition of "natural flavor." Like the FSIS's policy, a "natural flavor" must not undergo a synthetic process listed in 7 C.F.R. § 6502(21).<sup>119</sup> These synthetic processes include "process[es] that

113. *Id.*

114. FOOD SAFETY & INSPECTION SERV., *supra* note 59, at 109.

115. See Negowetti, *supra* note 1, at 332 (quoting *About FDA, What Is the Meaning of 'Natural' on the Label of Food?*, FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm214868.htm> (last updated Apr. 4, 2012)); See also FOOD SAFETY & INSPECTION SERV., *supra* note 59, at 109.

116. FOOD SAFETY & INSPECTION SERV., *supra* note 59, at 109. (on a case by case basis).

117. See Goodman, *supra* note 57, at 98 (citing Robert L. Smith et al., *A Procedure for the Safety Evaluation of Natural Complexes used as Ingredients in Food: Essential Oils*, 43 FOOD & CHEMICAL TOXICOLOGY 345, 348 (2005)) (stating that the most common source of natural flavors, essential oils, is not listed as an acceptable for natural claims).

118. See USDA, *supra* note 5 (stating that to be organic the producer must fill out an application and have a USDA accredited certifying agency approve the application).

119. 7 C.F.R. § 205.2 (2019).

chemically changes a substance extracted from a naturally occurring plant, animal, or mineral sources.”<sup>120</sup> Processes that occur in nature are not considered a synthetic process.<sup>121</sup> Additionally, unlike “natural flavors” within the FDA, “natural flavors” used in organic products cannot contain synthetic solvents.<sup>122</sup> The differences in what can be labelled as “natural flavor” in nonorganic products versus what can be labelled as “natural flavor” in organic products can cause confusion. “Natural flavor” in nonorganic products may include synthetic solvents and other incidental additives, while “natural flavor” in an organic product may not. This difference can be problematic because oftentimes consumers believe that the terms “natural” and “organic” are synonymous.<sup>123</sup> Even though organic products are considered separately within the Code of Federal Regulations, consumers could easily be confused on the differences because, despite being derived from different definitions, “natural flavor” will be labeled the same on both organic and non-organic products. Additionally, there is a fundamental difference in what is considered “natural” in products regulated solely by the FDA and those products that are both organic certified and regulated by the FDA because the FDA does not state whether a “natural” product can be more than minimally processed.<sup>124</sup>

The different policies created by the FDA and USDA regarding the use of “natural” and “natural flavor” create separate standards for what can be considered “natural.”<sup>125</sup> These standards may easily confuse both the consumer when reading labels while shopping for food, and the food industry attempting to properly label their products. This confusion reveals the need to have a unified definition of “natural” across the spectrum of food products. The FDA and the USDA should collaborate to create a standard definition of “natural.”<sup>126</sup> A uniform definition would

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120. 7 U.S.C. § 6502(22) (2019).

121. *Id.*

122. 7 C.F.R. § 205.605(a) (2019).

123. Negowetti, *supra* note 1, at 349 (quoting *Astiana v. Kashi Co.*, 291 F.R.D. 493, 508 (S.D. Cal. 2013)) (stating that consumers often “equate ‘natural’ with ‘organic’”).

124. *Id.* at 332 (quoting *About FDA, What Is the Meaning of ‘Natural’ on the Label of Food?*, FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm214868.htm> (last updated Apr. 4, 2012)).

125. *See id.* (quoting *About FDA, What Is the Meaning of ‘Natural’ on the Label of Food?*, FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm214868.htm> (last updated Apr. 4, 2012)) (FDA general policy); *See also* 21 C.F.R. § 101.22(a)(3) (2019) (FDA definition of natural flavor); *See also* FOOD SAFETY & INSPECTION SERV., *supra* note 59, at 109 (FSIS standard for natural products regulated by the USDA); *See also* 7 C.F.R. § 205.2 (2019) (definition of organic for natural purposes).

126. *See* Negowetti, *supra* note 1, at 329 (citing Citizen Petition from Robert G. Reinhard, Dir. Food Safety/Regulatory, Sara Lee Corp., to FDA, Requesting the Food and Drug Administration to Develop Requirements for the Use of the Term “Natural” Consistent with USDA’s Food Safety and Inspection Service 1-2 (Apr. 9, 2007), *available* at

help consumers understand what a “natural” label actually means on their products. The differences between what food products the FDA regulates versus the products the USDA regulates can confuse consumers,<sup>127</sup> and having different standards for “natural” between the two agencies is likely to confuse the consumer even further. A uniform standard would also help manufacturers producing products regulated both by the FDA and USDA correctly label their products in a simple and consistent manner. The current standards for “natural” and “natural flavor” set by the FDA and USDA are confusing. This confusion could be alleviated by a collaboration between the FDA and USDA to establish one consistent approach for use of the term “natural” and “natural flavors.”

Additionally, if the FDA and USDA establish one standard for both “natural” products and “natural flavors,” it would alleviate the issue shown in *Rice*, where the parties are using two separate regulations to try to prove their respective definition of “natural” is correct.<sup>128</sup> Courts may still have to interpret what the regulation means, but they will not need to figure out which regulation most closely applies in any given situation or develop their own standard when determining what “natural” means. Since there would only be one standard to apply, the courts would be able to more consistently determine whether a product is “natural.”

### *C. Potential Regulatory Requirements for the Use of the Term “Natural” on Food Products.*

#### 1. Aligning the FDA Standard with FSIS’s Current Standard

If the FDA adopted FSIS’s policy on “natural” labeling, the use of “natural” on food products would be substantially limited because most products would not meet the definition of minimally processed.<sup>129</sup> However, some “natural flavors” which are approved for use in organic products could be used in “natural” products, as long as the extraction process is physical and does not chemically alter the flavor.<sup>130</sup>

One main advantage of adopting the FSIS’s standard for “natural”

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<http://www.fda.gov/ohrms/dockets/dockets/07p0147/07p-0147-cp00001-02-vol1.pdf> (Sara Lee petitioned for the USDA and FDA to have a consistent definition of natural).

127. Richard A. Merrill & Jeffrey K. Francer, *Organizing Federal Food Safety Regulation*, 31 SETON HALL L. REV. 61, 118 (2000) (quoting U.S. COMM’N ON ORGANIZATION OF THE EXECUTIVE BRANCH OF GOVERNMENT, THE HOOVER COMM’N REPORT 250-51 (McGraw-Hill ed., 1949)) (stating that having multiple regulatory agencies governing food safety was confusing to the public).

128. See *Rice v. Nat’l Beverage Corp.*, No. 18 CV 7151, 2019 U.S. Dist. LEXIS 114961, at \*13-15 (N.D. Ill. July 11, 2019) (the plaintiffs use the definition of natural in the regulations giving organic requirements while LaCroix uses the FDA’s definition of natural flavor).

129. See FOOD SAFETY & INSPECTION SERV., *supra* note 59, at 109.

130. See *id.*

products is that it would more closely align with consumers' idea of what "natural" means.<sup>131</sup> Since a large reason the Food Drug and Cosmetic Act was enacted was to prevent food companies from misleading consumers, it would follow that how consumers interpret "natural" would be the best definition for the FDA and USDA to promulgate.<sup>132</sup>

Additionally, because most flavors would be excluded from products that can be labeled "natural,"<sup>133</sup> the issue of incidental additives present in *Rice* and *Graham* is alleviated. If most flavors cannot be included in "natural" products, synthetic ingredients present in products at extremely low levels as incidental additives through "natural flavors" would no longer be an issue. Therefore, litigation surrounding small amounts of synthetic substances in food products would most likely decrease.

Additionally, the issue in *Graham* and *Rice* where courts are forced to decide whose testing for synthetic ingredients is more accurate will also be alleviated by adopting the FSIS definition.<sup>134</sup> Like the issue with incidental additives, if most flavors are not allowed in "natural" products then testing for synthetic flavors or incidental additives is unlikely to occur because any flavor detected would block a product from being labeled "natural."

However, the FSIS does allow "natural flavors" in "natural" products if the flavor is either minimally processed or if the FSIS has evaluated the flavor and determined that "the use of [the] . . . ingredient [that has been more than minimally processed] would not significantly change the character of the product to the point that it could no longer be considered a natural product."<sup>135</sup> This exception could create a loophole that would allow small amounts of flavors or other additives to be in "natural" products. If the FSIS's policy was adopted and flavors were commonly added to the finished product under this exception, it may not prevent much litigation around small amounts of ingredients because flavors will still be present in "natural" products.

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131. See Negowetti, *supra* note 1, at 349 (quoting *Astiana v. Kashi Co.*, 291 F.R.D. 493, 508 (S.D. Cal. 2013)) (stating that consumers often "equate 'natural' with 'organic'").

132. *U.S. v. Bradshaw*, 840 F.2d 871, 874 (11th Cir. 1998) (stating the purpose of the FDCA is to protect consumers from misbranded products); See also 21 U.S.C. § 343 (2019) (states that a product is misbranded if it is misleading).

133. See Goodman, *supra* note 57, at 98 (citing Robert L. Smith et al., *A Procedure for the Safety Evaluation of Natural Complexes used as Ingredients in Food: Essential Oils*, 43 *Food & Chemical Toxicology* 345, 348 (2005)) (stating that the most common source of natural flavors, essential oils, is not listed as acceptable for natural claims).

134. See *Food, Flavor, & Beverage Authenticity Testing Facility*, *supra* note 97, (University of Georgia's testing to determine synthetic ingredients in food is accredited under the ISO/IEC 17025:2005 standards. This is the test that plaintiffs used in *Graham*); See also Defendant Nat'l Beverage Corp.'s Answer and Affirmative Defenses to Class Action Complaint, *supra* note 91, at 4 (stating that LaCroix tests its product using an independent third party laboratory that is also accredited by ISO).

135. FOOD SAFETY & INSPECTION SERV., *supra* note 59, at 109.

Furthermore, it is also likely that litigation may not be prevented because the FDA does not currently approve food product labels before they can be used.<sup>136</sup> The USDA can allow “natural flavoring” in products on a case by case basis because the USDA approves all labels before a food company uses the label.<sup>137</sup> The FDA could decide to start approving labels before food companies could label products containing “natural flavors” as “natural.” This would likely reduce litigation because, if the FDA approved the label, the food companies could rely on the FDA’s approval as a defense to any claims that their product is not “natural.” However, it is unlikely that the FDA would want to spend the extra money and time to approve these labels.<sup>138</sup> Therefore, food companies would have to independently determine whether their product is affected by the addition of “natural flavor.” If food companies determine whether the “natural flavor” significantly affects the finished product, it is unlikely that litigation will decrease.

One way to reduce litigation would be to use FSIS’s definition of “natural,” but remove the exception. However, this would severely limit the amount of “natural” foods in the marketplace. Many consumers want to buy products that are “natural,” and limiting foods that are normally “natural” may hinder consumers from buying products that they would consider to be natural because the food would not fall under the FSIS’s definition of “natural.”<sup>139</sup>

For the FSIS’s definition of “natural” to be effective in limiting litigation, the FDA would either have to ban “natural flavors” in “natural” products or take time to approve product labels to determine whether the use of “natural flavors” significantly changes the character of the food product. Since the FDA is unlikely to start approving all labels on food products, banning “natural flavors” in “natural” products would be the most likely outcome of the FDA aligning their definition of “natural” with FSIS. While it is ideal for the definition of “natural” to align more closely with what consumers believe is natural, banning “natural flavors” and products that are more than minimally processed would likely severely limit the amount of “natural” products that consumers would be able to buy. A more balanced approach that is relatively close to what consumers believe is natural, while still allowing a large range of products to be labeled “natural,” is ideal.

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136. See FDA, *supra* note 63, at 4.

137. See *Labeling.*, *supra* note 63.

138. See *Fact Sheet: FDA at a Glance*, *supra* note 31 (the FDA “regulates about 77% of the food supply.”). Based on the number of food products that the FDA regulates it would require a lot of manhours and money for the FDA to approve every label of products regulated by the FDA.

139. See Negowetti, *supra* note 1, at 329 (citing Mike Esterl, *The Natural Evolution of Food Labels*, WALL ST. J., Nov. 6, 2013, at B1) (consumers spent over forty billion dollars on natural products in 2013).

## 2. Modifying the FDA's Standard to Determine Whether a Product is Natural

While the FDA's current standard is confusing and has already caused significant litigation,<sup>140</sup> modifying the FDA's policy to clarify the definition of "synthetic" and set limits for incidental additives could be a thorough "natural" policy that meets most consumer expectations, allows for many "natural" options, and is not overly restrictive on the food industry.

First, the FDA would need to clarify what constitutes "synthetic."<sup>141</sup> More specifically, the FDA should clarify whether "synthetic" includes incidental additives and if an ingredient's processing determines whether the ingredient is "natural." If the FDA decided that incidental additives are included in determining whether a product is "synthetic," it would severely limit what is currently being labeled "natural." Food producers who are purchasing ingredients from other suppliers would need to ensure that "synthetic" incidental additives are not in any of the products that they purchase. This rule is especially true when producers purchase flavors because incidental additives do not affect whether a flavor is "natural."<sup>142</sup> This could lead to flavor manufacturers having to label more than the regulation requires to help food producers determine whether a finished food product is "natural."

Additionally, allowing incidental additives to affect whether a food is "natural," leaves open the problem of whether trace amounts of synthetic ingredients affect whether a food is "natural."<sup>143</sup> Because trace ingredients are in products at such a small level,<sup>144</sup> it is difficult for food producers to detect trace amounts of "synthetic" ingredients in their food products. Food producers may decide to stop using the term "natural" even if they believe that their products meet all of the FDA's "natural" requirements out of fear that there is a hidden "synthetic" incidental additive in their product. While ensuring that there are no synthetic incidental additives present in a food product may more closely align with

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140. See *supra* Part III. B. for an analysis.

141. Negowetti, *supra* note 1, at 332 (quoting *About FDA, What Is the Meaning of 'Natural' on the Label of Food?*, FOOD & DRUG ADMIN.FDA, <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm214868.htm> (last updated Apr. 4, 2012)) (stating that a food product can be labeled natural if "the food does not contain added color, artificial flavors, or synthetic substances").

142. See 21 C.F.R. § 101.22(h) (2019).

143. Lamonica et al., *supra* note 7, at 6 (stating that claims about trace amounts of pesticides in products is a trend in natural litigation).

144. See, e.g., *Doss v. Gen. Mills, Inc.*, No. 18-61924-Civ-Scola, 2019 U.S. Dist. LEXIS 100791, at \*2 (S.D. Fla. June 14, 2019) (stating that glyphosate was found in a General Mills product ranging between 470 – 1,125 parts per billion).

what consumers believe the term “natural” should be,<sup>145</sup> the amount of “natural” products available to consumers may significantly drop, regardless of whether the product meets “natural” requirements.

Including incidental additives in determining whether a product is “natural” will likely alleviate some of the challenges surrounding *Rice* and *Graham*. For example, it may not be necessary to determine which party’s test is more accurate. If there is an incidental additive that is “synthetic” in the product, it does not matter whether the flavoring ingredients are “natural” or not—the product cannot be labeled “natural.” The volume of cases surrounding the term “natural” is likely to decrease because food manufacturers are less likely to label their products “natural.”

The FDA could ease food manufacturers’ fears that a synthetic incidental additive got into their product through a “natural flavor” by changing the flavor regulations to include incidental additives when determining whether a flavor is “natural.” However, changing the definition of “natural flavor” would significantly impact the flavor industry, as many “natural flavors” use synthetic solvents. Therefore, the flavor industry would have to relabel their flavors as artificial or reformulate their flavors to only use natural solvents. The flavor industry would likely choose to label most of their products artificial rather than change their formulas, especially if there is not a natural alternative to the solvent that was used in the original flavor. Similar to food manufacturers not labeling products “natural” out of fear there is an unknown synthetic incidental additive in their product, flavor manufacturers may not label flavors “natural” out of fear that one of the flavoring ingredients contains a trace amount of a synthetic processing ingredient.

The FDA could determine that incidental additives do not affect whether a product can be labeled “natural.” If incidental additives do not affect whether a food is natural, the number of food producers deciding not to label their products “natural” should decrease because producers would no longer need to worry about unknown synthetic additives being in their products. This would allow products to be labeled “natural” when they only contain a low percentage of a synthetic ingredient that does not function in the finished food product. Allowing incidental additives in “natural” products may closely align with FSIS’s allowance of more than minimally processed food ingredients in “natural” products on a case by case basis,<sup>146</sup> but would allow food companies to make the determination

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145. See Negowetti, *supra* note 1, at 349 (quoting *Astiana v. Kashi Co.*, 291 F.R.D. 493, 508 (S.D. Cal. 2013)) (stating that consumers often “equate ‘natural’ with ‘organic’”); See also 7 C.F.R. § 205.605 (2019) (stating that organic flavors cannot be produced from synthetic ingredients or contain any synthetic solvents).

146. FOOD SAFETY & INSPECTION SERV., *supra* note 59, at 109.

so that the FDA does not need to approve the product labels. Prohibiting incidental additives from affecting whether a product is “natural” will likely reduce litigation surrounding whether a food product is “natural” because consumers will not prevail in cases where the ingredient in question is a trace ingredient. Reducing litigation will also decrease the likelihood that courts would have to make decisions around which party’s testing method is better.

However, one serious concern about excluding incidental additives when determining whether a product is “natural” is that food manufacturers will take advantage of this rule and call ingredients “incidental” that actually function in the product or are in the product at a high percentage in order to label their product “natural.” Additionally, by allowing incidental additives in “natural” products, how products are declared to be “natural” differs from consumer perception of what “natural” means.<sup>147</sup> Consumers often do not believe that there are any synthetic components within a “natural” food product, including incidental additives. Therefore, consumers may be confused that “natural” products can have small amounts of synthetic additives within them. Additionally, absent further clarification as to what the FDA considers an incidental additive, litigation about whether an ingredient is truly an incidental additive may increase.

One way that the FDA could reduce the likelihood of food manufacturers taking advantage of using incidental additives is to create caps and standards for specific ingredients and classes of ingredients that can be considered incidental when they are in food products. If the FDA sets a cap for the amount of an ingredient that can be in a food product while still being an incidental additive, it will strike a balance between what consumers believe “natural” means while providing food producers a reasonable path to call their products “natural.” While consumers may not be happy that there are any synthetic products in the “natural” foods that they purchase, the standards that the FDA would create should reassure consumers that any synthetic ingredient in a “natural” product is in the product at extremely low levels. Additionally, if the FDA chooses to take this path, it is likely that the variety of food products labeled “natural” will remain. The food industry may prefer to not label certain ingredients that do not function in their food at higher percentages than the FDA allows, but they would have confidence that when they claim an ingredient is incidental, and does not affect whether a product is “natural,” they should prevail in any “natural” litigation. Additionally, litigation around the term “natural” would likely decrease. If the issue in litigation

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147. See Negowetti, *supra* note 1, at 349 (quoting *Astiana v. Kashi Co.*, 291 F.R.D. 493, 508 (S.D. Cal. 2013)) (the same as organic).

is whether an incidental ingredient is synthetic in a product, as long as the incidental additive is not in the product at a higher percentage than the FDA allows, the food company will prevail. Courts will likely have an easier time determining whether an ingredient in a food product is over the limit set by the FDA than determining whether an incidental additive is synthetic and, if the incidental additive is synthetic, whether it is in a product at a level that should change whether the food is “natural.”

One problem with having the FDA set limits for incidental additives, and then not including those additives in determining whether a product is “natural” is that consumers do not want any synthetic ingredients in their food.<sup>148</sup> If the FDA allows incidental additives in products, educated consumers may not purchase “natural” products out of a belief that “natural” products should not contain any synthetic ingredients, regardless of the amount of the synthetic ingredient in the product. If consumers do not buy products labeled “natural” because they disagree with the FDA’s definition, then food producers may not label their products “natural” because it does not add value to their product.

While the FDA’s current policy is vague, modifying the definition to exclude incidental additives is likely to decrease litigation surrounding the term “natural.” Additionally, defining the acceptable levels ingredients can be in a product and still be considered incidental will better balance consumers’ beliefs about what the term “natural” should mean and create a realistic standard for the food industry that allows the industry to continue providing natural products to the market place.

#### IV. CONCLUSION

The FDA’s lack of an enforceable “natural” policy has led to confusion regarding which products can be labeled natural.<sup>149</sup> This confusion, alongside advances in scientific technology, has led to increased litigation regarding whether a product can be labeled “natural.”<sup>150</sup> However, if the FDA chooses to define and regulate the term natural, the amount of litigation and confusion could substantially decrease. Additionally, in the best case scenario, the FDA and USDA would align their definitions of the term “natural” to have one unified standard. However, since organic foods have their own certification process,<sup>151</sup> organic products should

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148. *See id.*

149. *See* Negowetti, *supra* note 1, at 329 (citing Mike Esterl, *The Natural Evolution of Food Labels*, WALL ST. J., Nov. 6, 2013, at B1) (stating that 47% of consumers don’t view the term “natural” as trustworthy).

150. Lamonica et al., *supra* note 7, at 3-4 (in 2008 there were 19 class actions filed against the food industry, in 2018 there were 158, the majority of which were filed in California and New York).

151. USDA, *supra* note 5 (stating that to be organic the producer must fill out an application and have a USDA accredited certifying agency approve the application).

keep their separate definition of “natural.”

One option is for the FDA to adopt the USDA’s current definition of “natural.” While this definition is advantageous because the USDA would not have to adjust their definition of “natural” to have a uniform policy with the FDA, it is not the best policy because the current definition would likely significantly diminish the amount of “natural” food options available to consumers. Additionally, this standard may be even more stringent than what consumers believe “natural” means, since most “natural flavors” will not be allowed in “natural” products because flavors in general are more than minimally processed. If the FDA wanted “natural flavors” to be included in “natural” products, they would have to amend the definition of “natural flavor” to exclude flavors that are more than minimally processed. Additionally, there may be an increase in litigation regarding which products are more than minimally processed.

The best option for the FDA would be to keep its current policy, but exclude incidental additives in determining whether a product is “natural.” However, the FDA should more closely regulate the levels at which ingredients can be in a food product and still be incidental in order to discourage food producers from taking advantage of the rule by stating that synthetic ingredients are incidental in their products when they are not. This solution is the best balance between allowing food producers to label their products “natural” without fear of litigation and what the consumer expects the term “natural” to mean. This solution would allow a wide variety of “natural” products to remain on the market, while having a stringent standard for the term “natural.” Additionally, by using this policy, the FDA will not need to change the definition of “natural flavor,” which is already regulated. Ideally, the USDA would adopt this standard of the term “natural” to alleviate consumer confusion between the different definitions of “natural” between meat and non-meat products under the current USDA standard. By adopting this new standard, litigation surrounding the “naturalness” of products due to the presence of incidental additives would also decrease because it would not matter whether the incidental additive was “natural.” Finally, by adopting this standard, courts would not have to decide the technical question of which party’s testing is better to detect the “naturalness” of incidental additives.

*Rice* and *Graham* demonstrate the need for a uniform and regulated definition of natural. By the FDA regulating the term “natural” to exclude incidental additives, the proper balance between consumer expectations of “natural” and what food companies can label as “natural” will be achieved.