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# Legal Issues with Federal Labeling of Genetically Engineered Food: In Brief

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## Summary

Genetically engineered (GE) foods, sometimes referred to as genetically modified foods (GMO foods), are foods that are derived from scientific methods used to introduce new traits or characteristics to an organism. The labeling of GE foods has been the subject of debate among members of the general public and federal and state governments since the introduction of GE foods to the food supply in the 1990s.

Federal law does not impose specific labeling requirements on a food just because it may or may not contain GE ingredients or was derived using GE techniques. The Food and Drug Administration (FDA) has yet to issue formal regulations and policies on the labeling of GE food. However, this absence of direct federal regulation does not mean that GE foods are free from any federal oversight. Instead, labels of GE foods follow the same federal labeling requirements and guidelines outlined in the Federal Food, Drug, and Cosmetic Act (FFDCA) as non-GE foods. These labeling requirements prohibit false or misleading labels and address material information that may be relevant to the consumption of that food. However, some states have enacted laws that specifically demand manufacturers disclose the presence of GE ingredients in certain foods on the label. The United States Department of Agriculture's (USDA's) oversight over organic meat and poultry products involves the regulation of GE ingredients. However, the discussion of such oversight is beyond the scope of this report.

In the context of this regulatory ambiguity, consumer claims in litigation concerning GE food often focus on allegedly misleading or deceptive terms on the label when the food contains GE ingredients. Defendants in these cases typically make a motion to dismiss the case on the basis of deference to the FDA's expertise in this area as articulated in the primary jurisdiction doctrine. However, courts have not consistently interpreted the primary jurisdiction doctrine (court deference to an agency when deciding an issue of first impression) in the context of GE labeling. This inconsistency has created further ambiguity concerning the broader issue of when courts should defer to the FDA's expertise if the FDA has repeatedly declined to take action on a particular regulatory issue.

Several bills have been introduced in the 114<sup>th</sup> Congress that address labeling of GE foods, including the Genetically Engineered Food Right-to-Know Act (H.R. 913, S. 511) and the Safe and Accurate Food Labeling Act of 2015 (H.R. 1599), the Biotechnology Food Labeling Uniformity Act (S. 2621), and S. 2609, which would amend the Agricultural Marketing Act of 1946. Generally these bills would amend the FFDCA to impose specific labeling requirements disclosing information about GE techniques used in the production of a particular food product.

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The labeling of genetically engineered (GE) foods, sometimes referred to as genetically modified foods (GMO foods), has been the subject of debate among members of the general public and federal and state governments. Certain state legislatures have responded to public demand for GE labeling by enacting state laws requiring such a labeling scheme. The Federal Food, Drug, & Cosmetic Act (FFDCA) does not impose specific labeling requirements on a food just because it may or may not contain GE ingredients or was derived using GE techniques. Additionally, the Food and Drug Administration (FDA) has yet to issue formal regulations and policies on the labeling of GE food.

However, this absence of direct federal regulation does not mean that GE foods are free from any federal oversight. Instead, labels of GE foods follow the same federal labeling requirements and guidelines outlined in the FFDCA and implementing regulations as non-GE foods. Despite this regulation, parties have brought claims against manufacturers of GE foods alleging that such products are mislabeled as “natural.” But, the courts, when faced with these claims, have inconsistently balanced the expectations of consumers and manufacturers with deference to FDA expertise in the context of GE food labeling. The United States Department of Agriculture’s (USDA’s) oversight over organic meat and poultry products involves the regulation of GE ingredients. However, the discussion of such oversight is beyond the scope of this report.

This report analyzes the federal laws and policies impacting the labeling of GE foods and the legal ambiguities that have arisen in the courts concerning this area of regulation. The report begins with a brief discussion about GE foods and the wider controversy of consuming foods derived from these techniques. The report then examines the current federal regulatory framework for food labeling and how these provisions may impact the labeling of GE foods. Next, the report analyzes legal issues relating to judicial deference to the FDA when claims involving the labeling of GE foods appear in court. The report concludes with a discussion about legislation introduced during the 114<sup>th</sup> Congress that would impose federal labeling requirements for GE foods.

## Genetically Engineered Foods

“Genetic engineering” refers to the scientific methods “use[d] to introduce new traits or characteristics to an organism.”<sup>1</sup> These procedures can create a tolerance to herbicides, promote resistance to viruses, increase yields, and alter acidic content.<sup>2</sup> “Genetically engineered foods” (GE foods), also referred to as “genetically modified foods” (GMO foods),<sup>3</sup> are foods that are derived from these methods or include ingredients that are derived from these methods. Food and ingredients from GE plants were first introduced into the food supply in the mid-1990s.<sup>4</sup> Common GE plants include corn, canola, soybean, and cotton. These plants, in the form of cornstarch, corn syrup, canola oil, and soybean oil, are used as ingredients in common food products, such as salad dressings, cereals, soups, breads, and snack foods.

The FDA has found that GE foods are generally as nutritious as traditionally bred plants.<sup>5</sup> The World Health Organization has reported that GE foods currently on the market are not likely to

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<sup>1</sup> FDA, “Questions & Answers on Food from Genetically Engineered Plants,” <http://www.fda.gov/food/foodscienceresearch/biotechnology/ucm346030.htm> (last visited Aug. 11, 2014) (hereinafter “FDA, Q & A”).

<sup>2</sup> Valery Federici, *Genetically Modified Food and Informed Consumer Choice: Comparing U.S. and E.U. Labeling Laws*, 35 *BROOK. J. INT’L L.* 515, 523 (2010).

<sup>3</sup> The Food and Drug Administration (FDA) considers “genetic engineering” to be a more precise term than “genetic modification.” This report will generally use variations of the term “genetic engineering.” FDA, Q & A, *supra* note 1.

<sup>4</sup> Federici, *supra* note 2, at 520.

<sup>5</sup> FDA, Q & A, *supra* note 1.

present human health risks.<sup>6</sup> However, some members of the public generally oppose GE foods and have demanded specific labeling requirements for food products containing GE ingredients.<sup>7</sup>

## **Labeling Requirements Impacting GE Foods**

Federal law does not impose specific labeling requirements on food just because it may or may not contain GE ingredients or was derived using GE techniques. Labels of GE foods follow the same federal labeling requirements and guidelines outlined in the FFDCAs as non-GE foods. The FDA has issued informal policy statements emphasizing its position that specific labeling requirements for GE foods are unnecessary because the general labeling provisions in the FFDCAs will guide and protect consumers. However, some states have enacted laws that specifically demand manufacturers disclose the presence of GE ingredients in certain foods on the label.

This section first examines the federal statutory requirements that the FDA has highlighted as particularly relevant to the labeling of GE foods. The section then reviews the informal policy statements issued by the FDA concerning GE food labeling and the state laws enacted to address this particular issue. The section concludes with a brief discussion about the use of the word “natural” on GE food labels.

### **The Federal Food, Drug, & Cosmetic Act**

While the FFDCAs do not differentiate between GE and non-GE foods regarding labeling requirements, the FDA has specifically highlighted Sections 403 and 201 as provisions that may potentially impact the labeling of GE foods. These sections enable the FDA to expressly require that specific information must appear on the food label.<sup>8</sup> Sections 403 and 201 were both enacted in 1938 before GE foods entered the food supply.<sup>9</sup>

In prohibiting misbranded foods, Section 403 enables consumers to choose foods wisely by ensuring that the labels communicate essential and accurate information. Section 403(a) states that a food is misbranded if its labeling is false or misleading in any particular.<sup>10</sup> Section 403(i) requires each ingredient listed in the label’s ingredient statement to bear the common or usual name.<sup>11</sup> Therefore, under these sections, if a GE food is significantly different from its traditional counterpart such that the common name no longer adequately describes the GE food, the name or the label should describe this difference; otherwise the label may mislead the consumer.<sup>12</sup>

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<sup>6</sup> World Health Organization, “20 Questions on Genetically Modified Foods,” <http://www.who.int/foodsafety/publications/biotech/20questions/en/> (last visited Aug. 19, 2014).

<sup>7</sup> For example, the Center for Food Safety, a national nonprofit advocacy organization, has petitioned Congress and state legislatures to require mandatory labeling of GE foods. The organization has reported that over 1.4 million people have submitted comments in support of the petition. Center for Food Safety, “GE Food Labeling: States Take Action,” <http://www.centerforfoodsafety.org/issues/976/ge-food-labeling/fact-sheets/3067/ge-food-labeling-states-take-action> (last visited Aug. 11, 2014). The Non-GMO Project, a nonprofit organization, reports that more than 60 countries do not consider GE foods to be safe. Non-GMO Project, “GMO Facts,” <http://www.nongmoproject.org/learn-more/> (last visited Aug. 11, 2014).

<sup>8</sup> Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering, 66 Fed. Reg. 4839-42 (Jan. 18, 2001) [hereinafter 2001 Policy].

<sup>9</sup> P.L. 75-717, The Food, Drug, and Cosmetic Act (1938), 52 Stat. 1040.

<sup>10</sup> 21 U.S.C. §343(a).

<sup>11</sup> 21 U.S.C. §343(i).

<sup>12</sup> See 2001 Policy, 66 Fed. Reg. 4839.

Similarly, Section 201(n) states that a label is misleading if it fails to reveal facts that are material in the light of representations made on the label, or in light of consequences that may result from the use of the food.<sup>13</sup> The legislative history reveals little about the meaning or scope of “material” in this provision. In the past, the FDA has required specific labeling on the basis of it being “material” information if the absence of such information would “(1) pose special health or environmental risks ... ; (2) mislead the consumer in light of other statements made on the label ... ; or (3) in cases where a consumer may assume that a food, because of its similarity to another food, has nutritional ... , or functional characteristics of the food it resembles when in fact it does not.”<sup>14</sup>

The FDA has concluded that the presence of GE ingredients/methods itself is not material information requiring explicit disclosure on a food label because “the agency is not aware of any information showing that foods derived by [GE] methods differ from other foods in any meaningful or uniform way.”<sup>15</sup> However, the FDA has highlighted scenarios where GE food may differ from its traditional counterparts in some fashion such as a different nutritional property.<sup>16</sup> According to the FDA, this difference, but not the fact that GE was used, may be material to the consumer under Section 201(n). For example, if the GE food includes an allergen that the consumers would not expect to be present based on the name of the food, the presence of that allergen must be disclosed on the label as “material” information, enabling the consumer to avoid certain health risks.<sup>17</sup>

### **“Natural” Labels**

The use of the word “natural” on labels of GE foods is often the source of deceptive and misleading legal complaints. Similar to the term “genetically engineered foods,” neither the FFDCFA nor the corresponding regulations directly define “natural” in the labeling context. The FDA has issued an informal policy that ultimately defines “natural” through exclusion. According to the FDA, “natural” on a food label “mean[s] that nothing artificial or synthetic (including all color additives regardless of source) has been included in, or been added to, a food that would not normally be expected to be in the food.”<sup>18</sup> The FDA has declined to establish a formal definition for “natural” through rulemaking.<sup>19</sup>

## **FDA Policy**

The FDA has not yet adopted a formal policy on the labeling of GE food, but has issued nonbinding guidance on this topic in 1992 and 2001.

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<sup>13</sup> 21 U.S.C. §321(n).

<sup>14</sup> FDA, “Draft Guidance For Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering,” <http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm059098.htm> (last visited Aug. 22, 2014).

<sup>15</sup> Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22991 (May 29, 1992) [hereinafter 1992 Policy].

<sup>16</sup> 2001 Policy, 66 Fed. Reg. 4839.

<sup>17</sup> See 2001 Policy, 66 Fed. Reg. 4839.

<sup>18</sup> Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2407 (Jan. 6, 1993).

<sup>19</sup> *Id.*

The FDA's 1992 policy statement addressed foods derived from new plant varieties, including plants developed using GE techniques.<sup>20</sup> This policy statement responded to requests received by the FDA from industry representatives, other government agencies, academia, and the general public, seeking clarification about the regulation of foods derived using GE techniques.<sup>21</sup> Under this policy, foods derived from GE are "regulated within the existing framework of the [FFDCA], the FDA's implementing regulations, and current practice, utilizing an approach identical in principle to that applied to foods developed by traditional plant breeding."<sup>22</sup> The FDA supported this position on GE regulation by emphasizing that the regulatory status of any food depends upon certain objective characteristics and the intended use of the food, irrespective of the method by which the food was developed.<sup>23</sup>

In 2001, the FDA issued draft guidance reaffirming its position that GE foods do not require special labeling.<sup>24</sup> The 2001 statement, however, also acknowledged public comments on the 1992 policy that emphasized the need for more information available to consumers about GE foods.<sup>25</sup> Responding to this request, the FDA's 2001 guidance encourages manufacturers to voluntarily label food products that have or have not been developed using GE "so that the labeling statement is truthful, not misleading, and scientifically valid" as already required by FFDCA provisions on food labeling.<sup>26</sup>

## **State Laws**

Several states have recently passed laws imposing specific labeling requirements on GE food.<sup>27</sup> Enacted in 2013, Connecticut's Act Concerning the Labeling of Genetically-Engineered Food provides that certain food items are misbranded unless labeled as "Produced with Genetic Engineering."<sup>28</sup> These foods include wholesale and retail food, raw agricultural commodities, and seeds or seed stock that are, or may have been, at least partially produced by GE.

In 2014, Maine enacted Act to Protect Maine Food Consumers' Right to Know about Genetically Engineered Food and Seed Stock, which requires any GE food or seed stock to be labeled as "Produced with Genetic Engineering."<sup>29</sup> GE foods that do not follow this requirement are subject to sanctions for misbranding. The act exempts restaurants, alcoholic beverages, and medical food from these labeling requirements.<sup>30</sup>

Enacted in 2014, Vermont's Act Relating to the Labeling of Food Produced With Genetic Engineering requires food that was produced either entirely or partially by GE to be labeled as such.<sup>31</sup> Labeling may include the phrases: "partially produced with genetic engineering," "may be

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<sup>20</sup> 1992 Policy, 57 Fed. Reg. 22984-01.

<sup>21</sup> 1992 Policy, 57 Fed. Reg. 22984.

<sup>22</sup> *Id.*

<sup>23</sup> *Id.*

<sup>24</sup> 2001 Policy, 66 Fed. Reg. 4840.

<sup>25</sup> *Id.*

<sup>26</sup> 2001 Policy Fed. Reg. 4841.

<sup>27</sup> This report addresses only state laws that have been enacted at the writing of this report and not bills that have been introduced.

<sup>28</sup> CONN. GEN. STAT. §21a-92c (2013).

<sup>29</sup> ME. REV. STAT. tit. 22, §2592 (2014).

<sup>30</sup> ME. REV. STAT. tit. 22, §2593 (2014).

<sup>31</sup> VT. STAT ANN. tit. 9 §3043 (2014).

produced with genetic engineering,” or “produced with genetic engineering.” The act also prohibits manufacturers from labeling the food as “natural” if produced entirely or in part from GE.<sup>32</sup> Foods exempted from these requirements include alcoholic beverages, processed food with GE materials that do not account for more than 0.9% of the food’s total weight, medical food, and food served in restaurants.<sup>33</sup>

Vermont’s GE labeling act will take effect on July 1, 2016.<sup>34</sup> However, both the Connecticut and Maine statutes contain a provision stating that the state will not enforce the labeling requirements outlined in the respective acts until a requisite number of states pass similar legislation.<sup>35</sup> These state laws raise various legal issues, such as whether the state labeling requirements violate the First Amendment rights of the manufacturers; whether the state laws are preempted by federal labeling requirements; and whether these laws place an impermissible burden on interstate commerce. Trade organizations have filed a lawsuit challenging the constitutionality of Vermont’s labeling law on these and other grounds.<sup>36</sup> However, potential legal issues with these state laws are beyond the scope of the report.

## **Litigation & Labeling of GE Foods**

Consumer claims in litigation concerning GE food often focus on allegedly misleading or deceptive terms on the label when the food contains GE ingredients. Defendants in these cases typically make a motion to dismiss the case based on deference to the FDA’s expertise in this area as articulated in the primary jurisdiction doctrine. However, courts have not consistently interpreted the primary jurisdiction doctrine in the context of GE labeling, creating some ambiguity as to when courts should defer to the FDA’s expertise if the FDA has repeatedly declined to take action on this particular labeling issue.

Consumers tend to bring these legal claims under state unfair competition laws and not the FFDCA, despite similarities in statutory language, because the FFDCA prohibits private litigants from suing to enforce compliance with the statute. Only the federal government may enforce the provisions under the FFDCA.<sup>37</sup>

This section begins with an explanation of the primary jurisdiction doctrine and the factors a court considers when applying this doctrine. Then, this section examines the role of the primary jurisdiction doctrine in cases where consumers have brought misleading and deceptive labeling claims against a defendant’s use of the term “natural” on GE foods labels.

### **Primary Jurisdiction Doctrine**

Courts invoke the primary jurisdiction doctrine when a controversy requires an agency’s expertise and uniformity of ruling. The primary jurisdiction doctrine permits courts to stay proceedings or

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<sup>32</sup> *Id.*

<sup>33</sup> VT. STAT ANN. tit. 9 §3044 (2014).

<sup>34</sup> 2014, Vt. Acts, No. 120, §7.

<sup>35</sup> CONN. GEN. STAT. §21a-92c (2013); ME. REV. STAT. tit. 22, §2595 (2014).

<sup>36</sup> See, e.g., Niraj Chokshi, *Vermont just passed the nation’s first GMO food labeling law. Now it prepares to get sued*, WASH. POST, May 9, 2014, <http://www.washingtonpost.com/blogs/govbeat/wp/2014/04/29/how-vermont-plans-to-defend-the-nations-first-gmo-law/>.

<sup>37</sup> 21 U.S.C. §337(a) (“all such proceedings for the enforcement ... of this chapter shall be by and in the name of the United States.”)



dismiss a complaint without prejudice “if a claim ‘requires resolution of an issue of first impression, or of a particularly complicated issue that Congress has committed to a regulatory agency.’”<sup>38</sup> Usually technical or policy issues that should be addressed in the first instance by the agency to which Congress has granted that particular regulatory authority trigger the primary jurisdiction doctrine.<sup>39</sup>

Courts weigh four factors when determining whether to apply this doctrine: “(1) the need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute that subjects an industry or activity to a comprehensive regulatory authority that (4) requires expertise or uniformity in administration.”<sup>40</sup> After a court has invoked the primary jurisdiction doctrine, the court may “refer” the issue to the relevant agency. This referral permits parties to then seek an administrative ruling.<sup>41</sup> However, a formal transfer mechanism between the court and the administrative agency does not exist as it is the parties’ responsibility to initiate the administrative proceeding.<sup>42</sup>

## **Application of the Primary Jurisdiction Doctrine to GE Food Labeling Claims**

Lawsuits brought by consumers against manufacturers of GE foods generally focus on the allegedly misleading use of the word “natural” on labels of GE foods. Consumers claim that the use of “natural” and similar phrases such as “100% natural” are misleading under state unfair competition laws because the food contains GE ingredients, which, according to the claimants, are not “natural.”<sup>43</sup> In these suits, defendants often file motions to dismiss based upon the doctrine of primary jurisdiction. Courts, however, have inconsistently applied this doctrine to these types of claims. While courts have at times deferred to the FDA and dismissed or stayed the proceedings, in other cases courts have found that the primary jurisdiction doctrine does not apply to natural/GE misleading claims, for primarily two reasons: (1) the misleading/deceptive claims are legal questions within the province of the courts and not the FDA, and (2) the FDA has refused to consider referrals by the courts to the agency in the past.

The primary jurisdiction doctrine triggers deference to the agency when the claim involves an issue of first impression more appropriately considered by the agency with its expertise in that particular area. Courts, which have refused to invoke this doctrine in GE labeling cases, have generally maintained that questions of deceptive labeling belong in the courts, and do not involve the expertise of the FDA as the questions are legal in nature requiring consideration of whether the defendant has violated a particular law. For example, in *Bohac v. General Mills, Inc.*, the plaintiff brought a class action suit against General Mills claiming that the company’s inclusion of “100% Natural” on its products’ labeling was deceptive and misleading under California unfair competition laws because of the presence of GE ingredients.<sup>44</sup> General Mills moved to stay the case on the grounds that the FDA has primary jurisdiction over the term “natural.” The court

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<sup>38</sup> Clark v. Time Warner Cable, 523 F.3d 1110, 1114 (9<sup>th</sup> Cir. 2008) (internal citations omitted).

<sup>39</sup> *Id.*

<sup>40</sup> Syntek Semiconductor Co., Ltd. v. Microchip Technology Inc., 307 F.3d 775, 781 (9<sup>th</sup> Cir. 2002).

<sup>41</sup> Clark, 523 F.3d at 1115 (internal citation omitted).

<sup>42</sup> *Id.*

<sup>43</sup> Case law has not addressed whether GE food labels using the term “natural” is deceptive and misleading as courts rarely consider the merits of the deceptive labeling claim for GE foods in these cases.

<sup>44</sup> *Bohac v. General Mills, Inc.*, No. 12-CV-05280-WHO, 2013 WL 5587924, at \*1 (N.D. Cal. Oct. 10, 2013).

disagreed, stating that defining “natural” is not an issue of first impression.<sup>45</sup> The court further explained that “determining whether a term is false or misleading is within the province of the courts” and does not require the expertise of the FDA.<sup>46</sup> Reaching a similar conclusion, the court in *Ault v. J.J. Smucker Co.* stated that a definition of “natural” from the FDA would not necessarily help to determine whether the consumer is deceived by “All Natural” on the food label when evaluating the plaintiff’s claim.<sup>47</sup> Similarly, the court in *Rojas v. General Mills, Inc.* stated that the FDA’s position on certain food labels may be relevant to the analysis of consumer deception, but it is not the “sole or dispositive factor.”<sup>48</sup>

As discussed above, when a court finds that the agency has primary jurisdiction over a particular issue, the court will “refer” the case to the agency. However, the FDA’s refusal to consider similar referrals in the past has discouraged certain courts from referring misleading “natural” claims. For example, in *Re Frito-Lay North America, Inc.*, the plaintiff claimed that Frito-Lay products were deceptively labeled as “All Natural” when the products contained GE ingredients.<sup>49</sup> Frito-Lay responded that the case should be dismissed or stayed pending a referral to the FDA pursuant to the primary jurisdiction doctrine.<sup>50</sup> The court disagreed and declined to apply the primary jurisdiction doctrine because the “FDA is unlikely to respond in a timely manner to any referral from this [c]ourt.”<sup>51</sup> The court in *Ault v. J.J. Smucker Co.* expanded upon this position, declaring that FDA’s past refusals of a referral for the plaintiff’s particular claim weighs against the court’s invocation of the doctrine of primary jurisdiction.<sup>52</sup>

Despite the arguments that these misleading claims are legal questions for the courts to consider, at least one court has deferred to the agency’s authority in this area. In *Cox v. Gruma Corp.*, the plaintiff brought a class action suit alleging that the defendant’s labeling of its food was false and misleading because the defendant indicated that the food was “natural,” when it contained corn grown from GE seeds.<sup>53</sup> The court dismissed the case on primary jurisdiction grounds finding that the FDA has regulatory authority over food labeling as granted by Congress.<sup>54</sup> Citing the Ninth Circuit decision in *Pom Wonderful v. Coca-Cola*, the court deferred to the FDA regulatory authority in this area.<sup>55</sup> Nevertheless, the court recognized that there is a regulatory “gaping hole” regarding natural claims and GE foods, where further clarification from the FDA may help both consumers and manufacturers.<sup>56</sup>

When making the motion to dismiss under the primary jurisdiction doctrine, defendants in these cases have argued that the primary jurisdiction doctrine should apply as the agency should receive deference in the food labeling area. The defendants in *Rojas v. General Mills* and *Cox v. Gruma* cite the Ninth Circuit decision of *Pom Wonderful v. Coca-Cola*, in which the court deferred to the

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<sup>45</sup> *Id.* at \*3.

<sup>46</sup> *Id.*

<sup>47</sup> *Ault v. J. M. Smucker Co.*, No. 13-Civ-3409, 2014 WL 1998235, at \*5 (S.D.N.Y. May 15, 2014).

<sup>48</sup> *Rojas v. General Mills, Inc.*, No. 12-CV-05099-WHO, 2013 WL 5568389, at \*4 (N.D. Cal. Oct. 9, 2013).

<sup>49</sup> *In re Frito-Lay North America, Inc., All Natural Litigation*, No. 12-MD-2413, 2013 WL 4647512, at \*1 (E.D.N.Y. Aug. 29, 2013).

<sup>50</sup> *Id.* at \*7.

<sup>51</sup> *Id.* at \*9.

<sup>52</sup> *Ault*, 2014 WL 1998235, at \*4.

<sup>53</sup> *Cox v. Gruma Corp.*, No. 12-CV-6502 YGR, 2013 WL 3828800, at \*1 (N.D. Cal. July 11, 2013).

<sup>54</sup> *Id.*

<sup>55</sup> *Id.* at \*2.

<sup>56</sup> *Id.* at \*1.

FDA and its authority and expertise in food labeling, as support for their motions to dismiss.<sup>57</sup> The U.S. Supreme Court, in June 2014, overturned the Ninth Circuit decision in *Pom Wonderful v. Coca-Cola*,<sup>58</sup> holding that FDA regulation in the particular area of juice labeling does not extend deference to the FDA that would preclude a competitor from bringing a federal unfair competition claim.<sup>59</sup> At the time of this report, it is unclear how the Court's holding in this case will impact GE food labeling and lower court deference to the FDA when the FDA has not yet promulgated specific regulations regarding these types of labels.

## Legislation in the 114<sup>th</sup> Congress

Several bills have also been introduced in the 114<sup>th</sup> Congress that address labeling of GE foods.

The Genetically Engineered Food Right-to-Know Act would amend the FFDCFA to classify any food as misbranded that has been GE or contains one or more GE ingredients, unless such information is clearly disclosed.<sup>60</sup> The bill would exempt any food that (1) is served in restaurants or other similar eating establishments, (2) is a medical food, (3) would be subject to such requirement solely because it was produced using a GE vaccine, or (4) would be subject to such requirement solely because it includes the use of a GE processing aid or enzyme.<sup>61</sup> The bill defines “genetically engineered” food as a material intended for human consumption that is an organism produced through the intentional use of GE, or the progeny of intended sexual or asexual reproduction (or both) of organisms that are the product of GE.<sup>62</sup>

The Safe and Accurate Food Labeling Act of 2015 would establish different certification programs and labeling requirements under the oversight of both the FDA and the USDA.<sup>63</sup> First, Section 101 of the bill would direct the FDA to continue its current premarket consultation process for food derived from new plant varieties, including GE plants.<sup>64</sup> Under the bill, the FDA may require that the labeling of food produced from, containing, or consisting of a GE plant display a statement to inform consumers of a difference between food so produced and a comparable non-genetically engineered food.<sup>65</sup> Under this proposed requirement, the FDA may require such labeling if the agency has determined that there is a material difference between the two foods and the disclosure of such difference is necessary to protect public health or to prevent the label from being false or misleading. Additionally, the bill would amend the Plant Protection Act<sup>66</sup> to create a notification program requiring those who plan to introduce into interstate commerce GE plants for the use of food to notify the Secretary of Health and Human Services (HHS), who must then evaluate the food under the premarket consultation process described

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<sup>57</sup> Cox, 2013 WL 3828800, at \*2; Rojas, 2013 WL 5568389, at \*4-5 (court denied this motion, declaring that the court's consideration of this claim would not undercut FDA authority).

<sup>58</sup> For more information about *Pom Wonderful v. Coca-Cola*, see CRS Report R43670, *Juice Labeling and Pom Wonderful v. Coca-Cola: A Legal Overview*, by Emily M. Lanza.

<sup>59</sup> See *Pom Wonderful LLC v. Coca-Cola Co.*, No. 12-761, slip op., at 2 (2014).

<sup>60</sup> H.R. 913, 114<sup>th</sup> Cong. (1<sup>st</sup> Sess. 2015), §3; S. 511, 114<sup>th</sup> Cong. (1<sup>st</sup> Sess. 2015), §3.

<sup>61</sup> *Id.*

<sup>62</sup> *Id.*

<sup>63</sup> H.R. 1599, 114<sup>th</sup> Cong. (1<sup>st</sup> Sess. 2015). This bill passed the U.S. House of Representatives on July 24, 2015, by recorded vote: 275-150.

<sup>64</sup> H.R. 1599, §101. This certification process was established under the FDA's policy statement “Food Derived from New Plant Varieties” (57 F.R. 22984).

<sup>65</sup> H.R. 1599, §101.

<sup>66</sup> 7 U.S.C. §7701 et seq.

above. The bill would then require the entity to submit the evaluation to the Secretary of Agriculture.<sup>67</sup> The bill's Section 201 would establish a voluntary GE food certification program within the USDA to govern label claims with respect to the use or non-use of GE in the production and process of food.<sup>68</sup> Section 301 of the bill would amend Section 403 of the FFDCFA to deem a food misbranded if its labeling contains an express or implied claim that food is "natural" unless the claim uses terms that have been defined by regulations promulgated by the FDA.<sup>69</sup> The bill also contains several provisions that would impact a state's regulation of GE food labeling.<sup>70</sup>

In February 2016, Senator Pat Roberts introduced a bill, S. 2609, that would establish a national voluntary bioengineered food labeling standard, overseen by the USDA.<sup>71</sup> Specifically, the bill would require the USDA to promulgate regulations that would outline the process the agency would follow to determine when a food may be labeled as bioengineered.<sup>72</sup> These regulations would also prohibit an express or implied claim that a food is or is not safe solely based on whether the food is bioengineered.<sup>73</sup> Additionally, the bill includes a provision with respect to preempting state laws relating to the labeling requirements of GE food in interstate commerce.<sup>74</sup> However, the bill would permit a state to establish food labeling requirements for bioengineered food in interstate commerce that are identical to the proposed voluntary labeling standard.<sup>75</sup>

In March 2016, Senator Merkley introduced S. 2621, the "Biotechnology Food Labeling Uniformity Act."<sup>76</sup> Unlike Senator Roberts's bill, this act would amend the FFDCFA by stating that a GE food would qualify as misbranded unless it bears a label stating that it is GE.<sup>77</sup> According to the bill, the mandatory label must include either the words "genetically engineered" or "GE" immediately following the common name of the GE ingredient, an asterisk that denotes GE ingredients, a statement disclosing that the food is produced with GE or contains GE ingredients, or a symbol established by the Secretary of HHS that would disclose the presence of a GE ingredient.<sup>78</sup> The misbranding provision would not apply to processed food that contains GE ingredients that do not account for more than nine-tenths of one percent of the total weight of the processed food; food that may be considered GE solely on the basis that it was subject to a GE vaccine at some point; and food that would be considered GE solely on the basis that it was produced using a GE processing aid.<sup>79</sup> Like the other GE labeling bills, this act also contains a federal preemption provision that intends to preempt state GE labeling requirements that are

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<sup>67</sup> *Id.*, §111.

<sup>68</sup> *Id.*, §201.

<sup>69</sup> *Id.*, §301.

<sup>70</sup> *Id.*, §§113, 203, 303. Currently, Vermont, Connecticut, and Maine are the only states with GE food labeling laws. Vermont's GE labeling act will take effect on July 1, 2016. However, both the Connecticut and Maine statutes contain a provision stating that the state will not enforce the labeling requirements outlined in the respective acts until a requisite number of states pass similar legislation.

<sup>71</sup> S. 2609, §1.

<sup>72</sup> *Id.* (proposed Section 293 of the Agricultural Marketing Act of 1946).

<sup>73</sup> *Id.*

<sup>74</sup> *Id.* (proposed Section 295 of the Agricultural Marketing Act of 1946).

<sup>75</sup> *Id.* (proposed Section 293 of the Agricultural Marketing Act of 1946).

<sup>76</sup> S. 2621.

<sup>77</sup> *Id.*, §2.

<sup>78</sup> *Id.*

<sup>79</sup> *Id.*

different from those that would be imposed by the act.<sup>80</sup> However, the bill would further clarify the intended scope of this preemption clause by also expressly stating that other food labeling laws or common law remedies would not be preempted.<sup>81</sup>

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<sup>80</sup> *Id.*, §4.

<sup>81</sup> *Id.*