

# Lessons from Nutritional Labeling on the 20th Anniversary of the NLEA: Applying the History of Food Labeling to the Future of Household Chemical Labeling

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*Sunlight is said to be the best of disinfectants . . .*

—Justice Louis D. Brandeis<sup>1</sup>

## I. INTRODUCTION

An average consumer looking to purchase a household chemical product<sup>2</sup> and seeking to evaluate the safety or environmental toxicity of that product by checking the ingredients on the label<sup>3</sup> would find her search fruitless. A container of Comet cleanser lists one ingredient on its label, sodium dichloro-s-triazinetrione dihydrate,<sup>4</sup>

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1. LOUIS D. BRANDEIS, *OTHER PEOPLE'S MONEY AND HOW THE BANKERS USE IT* 92 (1914).

2. While the Household Product Labeling Act uses the term “household products” to refer to “household cleaning products and similar products,” this Note employs a broader definition of the term, encompassing cosmetics, pesticides, and similar products, in addition to household cleaning products. Preamble, Household Product Labeling Act of 2009, S. 1697, 111th Cong.; Preamble, Household Product Labeling Act of 2009, H.R. 3057, 111th Cong.

3. Numerous ingredients in household chemical products pose potential hazards to both human health and the environment. A brief, but by no means comprehensive, introduction to these hazards is presented *infra* Part IV.

4. Prestige Brands, Inc., *Comet Disinfectant Powder*, COMET CLEANSER, <http://www.cometcleanser.com/disinfectant.htm> (last updated 2011); *see also Air Pollution Caused by*

while a bottle of Simple Green All-Purpose Cleaner reveals no ingredients on its label.<sup>5</sup> The label on a bottle of Christian Dior Poison Eau de Toilette spray lists “[a]lcohol, fragrance, and D&C violet No. 2,”<sup>6</sup> while the label on a canister of Febreze Air Effects Hawaiian Aloha air freshener lists “[o]dor eliminator, water, fragrance, non-flammable natural propellant, [and] quality control ingredients.”<sup>7</sup> Consumer rights organizations have found potentially hazardous unlisted chemicals in all of these products.<sup>8</sup>

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*Comet Disinfectant Powder Cleanser (Regular)*, ENVTL. WORKING GRP., <http://www.ewg.org/schoolcleaningsupplies/cleaningsuppliesoverview?id=200> (last updated 2011).

5. *Air Pollution Caused by Simple Green All-Purpose Cleaner/Degreaser/Deodorizer*, ENVTL. WORKING GRP., <http://www.ewg.org/schoolcleaningsupplies/cleaningsuppliesoverview?id=209> (last visited Sept. 20, 2011). While Simple Green’s website discloses some, but not all, additional ingredients under a voluntary ingredient disclosure program, a consumer would probably not have that information available at the point of purchase. See Sunshine Makers, Inc., *Simple Green All-Purpose Cleaner*, SIMPLE GREEN, [http://www.simplegreen.com/products\\_all\\_purpose\\_cleanser.php](http://www.simplegreen.com/products_all_purpose_cleanser.php) (last visited Sept. 14, 2011). Also, though Simple Green’s website reveals the presence of 2-butoxyethanol—a chemical presenting some health concerns—a consumer would not associate any of the disclosed ingredients with exposure to potentially toxic chemicals such as formaldehyde, acetaldehyde, or allylanisole, which the Environmental Working Group (EWG) found that the product released when used. See *id.*; *Air Pollution Caused by Simple Green All-Purpose Cleaner/Degreaser/Deodorizer*, *supra*. Such findings regarding a self-proclaimed “environmentally-sensitive non-toxic cleaner” present particular concerns. Sunshine Makers, Inc., *supra*.

6. Env’tl. Working Grp., *Christian Dior, Poison Eau de Toilette (2005 Formulation)*, EWG’S SKIN DEEP COSMETICS DATABASE, [http://www.ewg.org/skindeep/product/69493/Christian\\_Dior%2C\\_Poison\\_Eau\\_de\\_Toilette\\_%282005\\_formulation%29/](http://www.ewg.org/skindeep/product/69493/Christian_Dior%2C_Poison_Eau_de_Toilette_%282005_formulation%29/) (last visited Sept. 14, 2011).

7. *Air Pollution Caused by Febreze Air Effects (Hawaiian Aloha)*, ENVTL. WORKING GRP., <http://www.ewg.org/schoolcleaningsupplies/cleaningsuppliesoverview?id=219> (last visited Sept. 14, 2011).

8. The Environmental Working Group found that using Comet Disinfectant Powder Cleanser released formaldehyde, toluene, acetaldehyde, chloroform, benzene, and other chemicals linked with cancer, reproductive toxicity, hormone disruption, neurotoxicity, and asthma. *Air Pollution Caused by Comet Disinfectant Powder Cleanser (Regular)*, *supra* note 4; see also *infra* Part IV. The EWG found that Simple Green All-Purpose Cleaner released formaldehyde, acetaldehyde, allylanisole, 2-butoxyethanol, and other chemicals linked with cancer, neurotoxicity, hormone disruption, and asthma. *Air Pollution Caused by Simple Green All-Purpose Cleaner/Degreaser/Deodorizer*, *supra* note 5; see also *infra* Part IV. Consumers Union, a consumer advocacy and product evaluation organization, determined that Christian Dior Poison Eau de Toilette spray (“Poison”) contained Di(2-ethylhexyl) phthalate and diethyl phthalate, both members of the phthalate class of chemicals associated with reproductive toxicity, thyroid problems, cancer, and birth defects. Consumers Union of U.S., Inc., *Chemicals in Cosmetics, Fragrance Testing*, CONSUMERREPORTS.ORG, [http://www.consumerreports.org/cro/promos/shopping/shopsmart/winter-2007/what-you-should-know-about-chemicals-in-your-cosmetics/fragrance-testing/0701\\_cosmetics\\_fragrance.htm](http://www.consumerreports.org/cro/promos/shopping/shopsmart/winter-2007/what-you-should-know-about-chemicals-in-your-cosmetics/fragrance-testing/0701_cosmetics_fragrance.htm) (last visited Sept. 14, 2011); see also *infra* Part IV. A 2002 EWG study found even higher levels of phthalates in Poison bottles,

In contrast to these incomplete and uninformative examples of labeling, the food products on those same shelves display helpful labels.<sup>9</sup> The “Nutrition Facts” label, which assumed its present form following the implementation of the Nutrition Labeling and Education Act of 1990,<sup>10</sup> includes disclosure of all components within each food product as well as federally mandated nutrition and health information, such as the quantity of various nutrients and allergy warnings.<sup>11</sup> While the present label has become ubiquitous on food products sold in the United States, the label only developed through a series of federal laws passed over the course of the

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but a later 2008 EWG study found detectable levels in only one out of every four bottles, indicating that the manufacturer of Poison may be reformulating its products. *See* Consumers Union of U.S., Inc., *supra* (describing discrepancy in results from 2002 EWG study and 2007 Consumers Union study); JANE HOULIHAN ET AL., ENVTL. WORKING GRP., NOT TOO PRETTY: PHTHALATES, BEAUTY PRODUCTS, AND THE FDA 7, 10–12 (July 8, 2002), *available at* [http://safecosmetics.org/downloads/NotTooPretty\\_report.pdf](http://safecosmetics.org/downloads/NotTooPretty_report.pdf) (reporting results of 2002 study of name-brand beauty products, including Poison); LISA ARCHER ET AL., CAMPAIGN FOR SAFE COSMETICS, A LITTLE PRETTIER: COSMETIC COMPANIES DENY HEALTH PROBLEMS RELATED TO PHTHALATES, BUT ARE THEY SECRETLY REFORMULATING? A FOLLOW UP TO THE 2002 “NOT TOO PRETTY” REPORT 5 (Nov. 2008), *available at* [http://safecosmetics.org/downloads/A-Little-Prettier\\_Dec08.pdf](http://safecosmetics.org/downloads/A-Little-Prettier_Dec08.pdf) (comparing results of EWG’s 2008 study with its 2002 study). However, due to the lack of required public disclosures, the accuracy of this supposition remains unknown. *See id.* at 7. The 2008 study still found substantial quantities of phthalates in other fragrances. *Id.* at 5–6. Notwithstanding the European Union’s ban on two of the chemicals found in Poison for use in products sold in Europe, the industry has not admitted that phthalates pose any health risks. *Id.* at 3, 12; Council Directive 2003/15, of the European Parliament and of the Council of 27 February 2003 Amending Council Directive 76/768/EEC on the Approximation of the Laws of the Members States Relating to Cosmetic Products, 2003 O.J. (L 66) 29 (EC). The EWG found that Febreze Air Effects Hawaiian Aloha air freshener released acetaldehyde, ethyl acetate, and other chemicals linked with cancer and neurotoxicity. *Air Pollution Caused by Febreze Air Effects (Hawaiian Aloha)*, *supra* note 7. However, due to inadequate testing the composition and toxicity of most household chemical products remains unclear. *See* David Ewing Duncan, *The Pollution Within*, NAT’L GEOGRAPHIC, Oct. 2006, at 118, 133; ALEXANDRA SCRANTON, WOMEN’S VOICES FOR THE EARTH, *WHAT’S THAT SMELL? HOW THE PINE FOREST IN YOUR CLEANING PRODUCT MAY BE HAZARDOUS TO YOUR HEALTH* 6 (June 2010), *available at* [http://www.womensvoices.org/wp-content/uploads/2010/06/Whats\\_That\\_Smell.pdf](http://www.womensvoices.org/wp-content/uploads/2010/06/Whats_That_Smell.pdf). The health effects of low-dose exposure to these chemicals over time, and to any combinations that those chemicals may form when released into the environment, remain unclear. *See* Duncan, *supra*, at 122–33; *see also infra* note 380 and accompanying text. In addition, many of these chemicals may harm the environment. *See infra* Part IV.

9. *See* 21 C.F.R. § 101 (2009) (Food and Drug Administration regulations outlining requirements for food labeling).

10. Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, § 2, 104 Stat. 2353–57 (codified as amended at 21 U.S.C. § 343).

11. 21 C.F.R. § 101.

twentieth century.<sup>12</sup> These laws were brought about through public and political pressure and mandated increasingly detailed disclosures.<sup>13</sup> Labeling progressed from the Pure Food and Drug Act of 1906, which required little more than truthful labeling regarding the contents of a food package,<sup>14</sup> to the detailed and relatively comprehensive label of the present day.<sup>15</sup> Over the course of this history, food product labeling evolved into a clear, accurate, and informative source of nutrition data for consumers at the point of sale.<sup>16</sup>

The present dysfunctional state of household chemical labeling came about through a combination of insufficient action by Congress and bureaucratic inertia on the part of the federal agencies responsible for chemical product regulation.<sup>17</sup> The current labeling regulations for most chemical products lack full ingredient disclosure, limiting the ability of consumers to select products without chemicals they wish to avoid.<sup>18</sup> At the same time, the Consumer Product Safety Act, the Federal Hazardous Substances Act, the Toxic Substances Control Act, and the regulations issued pursuant to them have burdened the enforcement process for those regulations with onerous evidentiary requirements and a lack of adequate information to evaluate the safety of chemicals.<sup>19</sup> For cosmetics, the Food, Drug, and Cosmetic Act, and the FDA's regulations issued pursuant to it, lack essential pre-market testing

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12. See *infra* Part II.

13. Jean Lyons & Martha Rumore, *Food Labeling-Then and Now*, 2 J. PHARMACY & L. 171, 173–81 (1993).

14. Pure Food and Drugs Act of 1906, ch 3915 § 1, 34 Stat. 768.

15. Despite the relatively comprehensive statements on modern food labels, debate continues over the need to label genetic modifications and other currently undisclosed attributes of food products. See *infra* note 113.

16. See *infra* note 385.

17. See *infra* Part V.A; see also Rachael Rawlins, *Teething on Toxins: In Search of Regulatory Solutions for Toys and Cosmetics*, 20 FORDHAM ENVTL. L. REV. 1, 23–30 (2009) (detailing the history of government inaction concerning the labeling of potentially hazardous products).

18. See *infra* Part V.A; see also SCRANTON, *supra* note 8, at 6.

19. See Rawlins, *supra* note 17, at 23–35 (discussing the procedural and evidentiary burdens of the FHSA and the CPSA); Michael P. Wilson & Megan R. Schwarzman, *Toward a New U.S. Chemicals Policy: Rebuilding the Foundation to Advance New Science, Green Chemistry, and Environmental Health*, 117 ENVTL. HEALTH PERSP. 1202, 1204–05 (2009) (discussing the Toxic Substances Control Act).

requirements and contain substantial loopholes.<sup>20</sup> Moreover, the FDA has failed to adequately enforce the existing regulations.<sup>21</sup> The maze of federal chemical safety regulations administered by the Consumer Product Safety Commission (CPSC or the Commission), the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and other federal and state entities has drastically limited consumers' capacity to protect themselves against the effects of a wide variety of potentially harmful chemical substances.<sup>22</sup>

To remedy the defects of the current household chemical labeling system, Senator Al Franken of Minnesota and Representative Steve Israel of New York introduced legislation in the 111th Congress that would mandate labeling of "household cleaning products and similar products" with disclosure of all ingredients.<sup>23</sup> This Note adopts that position as a starting point and proposes a new labeling scheme for all household chemicals<sup>24</sup> modeled on the "Nutrition Facts" label mandated for food products. The Note reviews the history of food labeling regulation, examines present household chemical regulations, and proposes a new regulatory regime that learns from the successes and failures of food labeling past and present.<sup>25</sup> Part II discusses the history of food and nutritional labeling since 1900.<sup>26</sup> Part III features an overview of current household chemical labeling regulations.<sup>27</sup> Part IV contains a brief introduction to some of the chemicals found in household products, including some of the known and suspected health and environmental concerns they may pose.<sup>28</sup> Part V analyzes potential regulatory solutions to the problems

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20. See notes 157–67 and accompanying text; see also Part V.F.

21. See Rawlins, *supra* note 17, at 9–16; see also *infra* Part V.A.

22. For a selection of the types of hazards presented by some of the common ingredients in household chemical products, see *infra* Part IV.

23. Household Product Labeling Act of 2009, S. 1697, 111th Cong.; Household Product Labeling Act of 2009, H.R. 3057, 111th Cong.

24. The proposed scheme for all household chemicals expands the scope of the current bill, which does not affect cosmetics or pesticides. See S. 1697 § 2(a)(2); H.R. 3057 § 2(b); see also 15 U.S.C. § 1261(f)(2) (2006) (excluding certain pesticides and cosmetics from the definition of "hazardous substance" under the FHSA).

25. See *infra* Part V.

26. See *infra* Part II.

27. See *infra* Part III.

28. See *infra* Part IV.

presented by the current state of household chemical labeling and suggests some forms that a new labeling scheme should adopt.<sup>29</sup>

## II. THE HISTORY OF FOOD LABELING

American regulation of food adulteration and misbranding began in earnest at the dawn of the twentieth century.<sup>30</sup> The rise of corporate food producers over the previous century, and America's increasing urbanization, resulted in a powerful food processing industry which accounted for 20 percent of America's manufacturing by 1900.<sup>31</sup> The industry's powerful government lobby, in conjunction with scant regulation, resulted in products that posed substantial threats to public health.<sup>32</sup> Spurred by the work of crusading government chemists such as Dr. Harvey W. Wiley,<sup>33</sup> and lurid depictions of the American food

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29. See *infra* Part V.

30. See Eric F. Greenberg, *The Changing Food Label: The Nutrition Labeling and Education Act of 1990*, 3 LOY. CONSUMER L. REP. 10, 10 (1990) (explaining the birth of such regulation with the PFDA in 1906). While prior legislation addressed tea, oleomargarine, and meat products, among others, those laws primarily responded to economic concerns regarding foreign trade and competition among domestic industries. Peter Barton Hutt & Peter Barton Hutt II, *A History of Government Regulation of Adulteration and Misbranding of Food*, 39 FOOD DRUG COSM. L.J. 2, 45–47 (1984). A 1902 law still in force today requires accurate labeling regarding the location of the origin of food products. *Id.* at 47; Act of July 1, 1902, ch. 1357, § 1, 32 Stat. 632, 632 (codified at 21 U.S.C. § 16 (2006)). Some state laws addressed the adulteration of certain food products such as flour, vinegar, candy, and dairy products, but the PFDA represented the first federal attempt at broad, industry-wide regulation to limit food adulteration and misbranding to protect public health. See Hutt & Hutt, *supra*, at 40–44, 47–53, 59.

31. HARVEY A. LEVENSTEIN, *REVOLUTION AT THE TABLE: THE TRANSFORMATION OF THE AMERICAN DIET* 30–43 (Univ. of Cal. Press 2003) (1988).

32. See PHILIP J. HILTS, *PROTECTING AMERICA'S HEALTH: THE FDA, BUSINESS, AND ONE HUNDRED YEARS OF REGULATION* 43–52 (2003) (explaining the battle against regulation).

33. As Dr. Harvey W. Wiley put it, “[t]he consumer has a right not be defrauded. It is more than a question of the pocketbook-and I will be glad when the money standard is not always brought up in this country-it is a great moral question. Fraud and deception are not necessary to business.” *Avoid Near-Foods, Dr. Wiley's Warning*, N.Y. TIMES, Apr. 4, 1909, available at <http://query.nytimes.com/mem/archive-free/pdf?res=F10A1FFB3E5A12738DDDA0894DC405B898CF1D3> (internal quotation marks omitted); see also HILTS, *supra* note 32, at 35–43. Wiley, later the first commissioner of the FDA, tested the toxicity of food adulterants by feeding them to a team of volunteers (the “Poison Squad”) and recording the results. JAMES HARVEY YOUNG, *PURE FOOD: SECURING THE FEDERAL FOOD AND DRUGS ACT OF 1906* 151–56 (1989); Harvey W. Wiley, *Pioneer Consumer Activist*, 40 FDA CONSUMER 34–35 (2006), available at <http://www.fda.gov/AboutFDA/WhatWeDo/History/CentennialofFDA/HarveyW.Wiley/default.htm>. There were reports of food products containing arsenic, sulfuric acid, wood chips, formaldehyde, borax, tree leaves, bark, and saltpeter, among other dangerous ingredients.

industry in periodicals and books such as Upton Sinclair's *The Jungle*,<sup>34</sup> Congress passed the Pure Food and Drugs Act of 1906 (PFDA).<sup>35</sup> The PFDA forbade the production of "any article of food or drug which is adulterated or misbranded,"<sup>36</sup> banned its sale in interstate commerce and to foreign purchasers (unless with permission of the foreign country),<sup>37</sup> and provided for "examinations of specimens of foods" by the Bureau of Chemistry of the United States Department of Agriculture (USDA).<sup>38</sup> As passed in 1906, the PFDA had no affirmative labeling requirement; instead, it merely required that any label applied to food packaging accurately reflect the product within the package.<sup>39</sup> However, the 1913 Gould Amendment mandated that "the quantity of the contents be . . . conspicuously marked on the outside of the package in terms of weight, measure, or numerical count."<sup>40</sup> Thus, the PFDA as amended

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David A. Kessler, *The Evolution of National Nutrition Policy*, 15 ANN. REV. NUTRITION xiii, xv (1995); Lyons & Rumore, *supra* note 13, at 173.

34. While Sinclair intended his book to expose the miserable working conditions of slaughterhouse workers, passages describing the unsanitary methods of meat production captured the public's attention. Eric Schlosser, *Foreword* to UPTON SINCLAIR, *THE JUNGLE* vii, xi (Penguin Books 2006) (1906). The Federal Meat Inspection Act of 1906, passed within days of the PFDA, established inspection and meat quality provisions for the meat industry. Hutt & Hutt, *supra* note 30, at 53–54; Federal Meat Inspection Act of 1906, ch. 3913, 34 Stat. 669, 674–79 (codified as amended at 21 U.S.C. §§ 601–625 (2006)). However, concern about the quality of food products had been building since the latter part of the previous century. See, e.g., ELLEN H. RICHARDS, *FOOD MATERIALS AND THEIR ADULTERATIONS* (Boston, Estes & Lauriat n.d.).

35. HILTS, *supra* note 32, at 43–53. The PFDA also obtained broad support from many major food manufacturers eager to calm public fears regarding their products and to decrease costs resulting from compliance with differing state laws. Ilyse D. Barkan, *Industry Invites Regulation: The Passage of the Pure Food and Drug Act of 1906*, 75 AM. J. PUB. HEALTH 18, 23–25 (1985); Wallace F. Janssen, *Outline of the History of U.S. Drug Regulation and Labeling*, 36 FOOD DRUG COSM. L.J. 420, 426 (1981).

36. Pure Food and Drugs Act of 1906, ch. 3915, § 1, 34 Stat. 768, 768. The PFDA defined food as "adulterated" if any substance had been removed or substituted, if ingredients were added intentionally to "injuriously affect its quality or strength," if the food "contain[ed] any added poisonous or . . . deleterious ingredient," or if it contained "a filthy, decomposed, or putrid animal or vegetable substance, or any portion of an animal unfit for food." *Id.* § 7. The PFDA also defined a "misbranded" food product as one that bore "any statement, design, or device regarding such article, or the ingredients or substances contained therein which shall be false or misleading in any particular." *Id.* § 8.

37. *Id.* § 2.

38. *Id.* § 3–4.

39. See *id.* § 8.

40. Gould Amendment, ch. 117, § 1, 37 Stat. 732, 732 (1913).

in 1913 represented the first substantial step toward the modern nutritional labeling scheme.<sup>41</sup>

Despite its significance as groundbreaking legislation, the 1906 Act left many deceptive practices unchecked. While the new law prohibited blatant falsehoods on labels, it placed the burden of proof to prove a label or claim false on the government rather than on the manufacturer to defend its accuracy.<sup>42</sup> The Supreme Court held in *United States v. Johnson*<sup>43</sup> that the PFDA's misbranding language only applied to those "false statements . . . [which] determine the identity of the article," thus largely limiting the Act's scope to false labeling regarding the identity of products rather than to any health claims on the packaging.<sup>44</sup> The language of the 1912 Sherley Amendment, passed to correct this decision, created additional problems by requiring the government to prove that a manufacturer had intended to mislead the public in order to find a violation.<sup>45</sup> The PFDA also mandated accurate statements on labels, but this did not apply to advertising outside of the product's packaging.<sup>46</sup> The law's lack of firm standards regarding what constituted food adulteration and of any requirement that producers report the ingredients of their products meant that food products frequently did not contain the ingredients consumers would expect.<sup>47</sup> By the 1930s, the flaws in the PFDA, and the relatively regulation-friendly atmosphere of the New Deal era, prompted the next step in food labeling regulation.<sup>48</sup>

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41. Lyons & Rumore, *supra* note 13, at 173.

42. HILTS, *supra* note 32, at 54. For comprehensive and contemporaneous descriptions of the food preparation methods, adulteration problems, and food labeling laws of the period as observed by Dr. Wiley, see HARVEY WASHINGTON WILEY, *FOODS AND THEIR ADULTERATION* (1907) and HARVEY W. WILEY, *1001 TESTS OF FOODS, BEVERAGES AND TOILET ACCESSORIES* (1914).

43. *United States v. Johnson*, 221 U.S. 488 (1911).

44. *Id.* at 497–98.

45. CHARLES O. JACKSON, *FOOD AND DRUG LEGISLATION IN THE NEW DEAL* 4 (1970). Proving intent substantially hampered prosecution, and even if the government achieved a conviction, a violation merely counted as a misdemeanor bringing with it only a \$200 fine for a first offense. HILTS, *supra* note 32, at 54–61.

46. HILTS, *supra* note 32, at 54.

47. See Janssen, *supra* note 35, at 428.

48. Hutt & Hutt, *supra* note 30, at 61–62. Like the negative press that surrounded the food industry preceding the 1906 Act, a major news event helped provide the impetus for passage of the 1938 Act. See Michelle Meadows, *A Century of Ensuring Safe Foods and Cosmetics*, 40 *FDA CONSUMER* 6, 8 (2006) (“[I]t wasn’t until a drug-related tragedy occurred that a new food



In 1938, Congress passed the Food, Drug, and Cosmetic Act (FD&C Act), intending to repair many of the holes in the previous legislation.<sup>49</sup> The FD&C Act carried over much of the language concerning the adulteration of food products<sup>50</sup> from the PFDA, but also granted the FDA authorization to create new food standards for identity, quality, and fill of container.<sup>51</sup> In response, the FDA composed a plethora of standards for specific food products.<sup>52</sup> These standards helped eliminate the previous uncertainty that had hampered enforcement of the PFDA.<sup>53</sup> The broad authority granted under the FD&C Act permitted the FDA to define the characteristics of various standardized foods and required the food industry to conform to those standards.<sup>54</sup>

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and drug law was passed. After 107 people died from a poisonous ingredient in a product called Elixir Sulfanilamide, Congress passed the Food, Drug, and Cosmetic Act (FD&C Act) with new provisions in 1938"); Federal Food, Drug, and Cosmetic Act, ch. 675, § 401, 52 Stat. 1040, 1046 (1938) (codified as amended at 21 U.S.C. §§ 301–399(a) (2006)). The FDA created an exhibit called the "Chamber of Horrors" that featured particularly objectionable examples of products on the market under the current law. HILTS, *supra* note 32, at 84. As in the period leading up to the PFDA, several notable books also exposed some of the more glaring faults of the contemporary food regulation system. *See, e.g.*, RUTH DEFOREST LAMB, AMERICAN CHAMBER OF HORRORS: THE TRUTH ABOUT FOOD AND DRUGS (Arno Press 1976) (1936); ARTHUR KALLET & F.J. SCHLINK, 100,000,000 GUINEA PIGS: DANGERS IN EVERYDAY FOODS, DRUGS, AND COSMETICS (1932).

49. Hutt & Hutt, *supra* note 30, at 61–62.

50. Federal Food, Drug, and Cosmetic Act § 402. While the FD&C Act added specific requirements such as banning containers composed in part of "deleterious substance[s]," limiting the use of "coal-tar color[s]," and restricting certain ingredients in confectionery, the language regarding adulteration of food remained substantially the same. *See id.* §§ 301, 402.

51. Meadows, *supra* note 48, at 8.

52. Hutt & Hutt, *supra* note 30, at 64–65. The standards of identity proved extremely important in later decades, when the FDA developed standards for the enrichment and fortification of food products. *Id.* at 65. The years leading up to and following the FD&C Act saw the introduction of many new vitamin additives, and brought recognition of the importance of various nutrients to human health. HARVEY LEVENSTEIN, PARADOX OF PLENTY: A SOCIAL HISTORY OF EATING IN MODERN AMERICA 13–23 (Univ. of Cal. Press rev. ed. 2003) (1993). As methods for adding these nutrients to food became available, pressure on the FDA from sources such as the American Medical Association resulted in various new food standards, each defining the ingredients that manufacturers could use to create specific food products. Hutt & Hutt, *supra* note 30, at 65. In 1972, the FDA abandoned the "recipe" approach and amended the standards to allow all "safe and suitable" ingredients while requiring more substantial nutritional labeling. *Id.*; *see also* Dale Blumenthal, *A New Look at Food Labeling*, 23 FDA CONSUMER 15, 15 (1989).

53. Blumenthal, *supra* note 52, at 15. The FD&C Act also removed the government's burden to prove fraudulent intent when enforcing violations. Greenberg, *supra* note 30, at 10.

54. Hutt & Hutt, *supra* note 30, at 64–65.

The FD&C Act also provided far more robust and detailed requirements concerning the misbranding of food items.<sup>55</sup> In addition to the standardization clauses, the FD&C Act mandated extensive packaging and labeling regulation.<sup>56</sup> As well as banning all “false or misleading” labeling, the FD&C Act restricted the sale of products under the name of other foods, imitations of food products not identified as such, and packages “made, formed, or filled” in a misleading manner.<sup>57</sup> It also proscribed the sale of products for which the FDA had created “definition[s] and standard[s] of identity” unless the products conformed to those definitions and standards.<sup>58</sup> The FD&C Act required all packaged foods to bear a label featuring the “name and place of business of the manufacturer, packer, or distributor,” as well as “the quantity of the contents in terms of weight, measure, or numerical count.”<sup>59</sup> If the FDA had not created a standard of identity for a specific product, the FD&C Act also mandated labeling that included “the common or usual name of the food, if any there be” and “the common or usual name of each . . . ingredient” where the product was made from two or more ingredients, except for “spices, flavorings, and colors.”<sup>60</sup> The FD&C Act also required all regulated packaging to prominently display all information required by it.<sup>61</sup> By requiring the “common or usual name[s]” of food products and mandating ingredient reporting, the

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55. Federal Food, Drug, and Cosmetic Act § 403.

56. *Id.*

57. *Id.*

58. *Id.*

59. *Id.* Labeling under the FD&C Act encompassed “all labels and other written, printed, or graphic matters (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.” *Id.* § 201(m). Courts have broadly interpreted this provision. See Roseann B. Termini, *The Prevention of Misbranded Food Labeling: The Nutrition Labeling and Education Act of 1990 and Alternative Enforcement Mechanisms*, 18 OHIO N.U. L. REV. 77, 81–84 (1991) (discussing the seminal Supreme Court case *United States v. Kordel*, 335 U.S. 345 (1948) and its progeny). For example, the First Circuit held in *V. E. Irons, Inc. v. United States* that it is “clear that the term ‘labeling’ must be given a broad meaning to include all literature used in the sale of food and drugs, whether or not it is shipped into interstate commerce along with the article.” *V. E. Irons, Inc. v. United States*, 244 F.2d 34, 39 (1st Cir. 1957).

60. Food, Drug, and Cosmetic Act § 403(i).

61. Food, Drug, and Cosmetic Act § 403(f).

FD&C Act adopted a more consumer-oriented approach to labeling<sup>62</sup> and provided the basis for much of modern food labeling regulation.<sup>63</sup>

The decades following the passage of the FD&C Act saw a parade of amendments further defining its scope.<sup>64</sup> The 1954 Miller Pesticide Amendment granted the FDA authority to establish acceptable levels of pesticide residues in food products.<sup>65</sup> The Food Additives Amendment of 1958 defined all food additives as unsafe unless they conformed to the FD&C Act or were “generally recognized . . . to be safe” and in use before passage of the Amendment.<sup>66</sup> If a food additive did not meet the latter requirement, food manufacturers had to petition for approval of its use.<sup>67</sup> The Color Additives Amendment of 1960 contained similar provisions for coloring agents.<sup>68</sup> The Fair Packaging and Labeling Act of 1966 (FPLA) mandated labeling with regard to the quantity of contents, identity of product, name of manufacturer, and serving size for a wide range of consumer

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62. Meadows, *supra* note 48, at 8.

63. Kessler, *supra* note 33, at xv.

64. Hutt & Hutt, *supra* note 30, at 62.

65. Greenberg, *supra* note 30, at 10; Miller Pesticide Amendment, ch. 559, 68 Stat. 511 (1954). The Environmental Protection Agency now has the responsibility for determining acceptable levels of pesticide residues, but the FDA still has authority to enforce those levels. Greenberg, *supra* note 30, at 10.

66. Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784 (codified as amended at 21 U.S.C. § 348). The Food Additives Amendment exempted a long list of additives, deemed “generally recognized . . . to be safe” and in use before its passage, from any new testing or verification. *Id.*; WARREN J. BELASCO, APPETITE FOR CHANGE: HOW THE COUNTERCULTURE TOOK ON THE FOOD INDUSTRY 135–36 (Cornell Univ. Press 2d updated ed. 2007) (1989). The Delaney Clause established a zero-tolerance standard for additives found to cause cancer in animals. Ray Thornton, *Preface* to COMM. ON SCIENTIFIC AND REGULATORY ISSUES UNDERLYING PESTICIDE USE PATTERNS AND AGRIC. INNOVATION ET AL, REGULATING PESTICIDES IN FOOD: THE DELANEY PARADOX, at v (1987); Food Additives Amendment sec. 4 § 409(c)(3)(A). In 1996, Congress passed the Food Quality Protection Act, which revoked the Delaney Clause as applied to pesticides but imposed a general “reasonable certainty of no harm” standard for pesticide residues, a stricter standard than previously employed, other than for pesticides previously falling within the scope of the Clause. Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489, 1514 (codified as amended in scattered sections of 21 U.S.C. § 342 (2006)); *Food Quality Protection Act (FQPA) of 1996*, ENVTL. PROTECTION AGENCY, <http://www.epa.gov/pesticides/regulating/laws/fqpa> (last updated Sept. 9, 2011). However, the Delaney Clause remains in effect for other food additives, such as coloring agents, animal drugs, and other chemicals. Richard A. Merrill, *Food Safety Regulation: Reforming the Delaney Clause*, 18 ANN. REV. PUB. HEALTH 313, 333–34 (1997).

67. Food Additives Amendment, Pub. L. No. 85-929, *supra* note 66.

68. Kessler, *supra* note 33, at xvi; Color Additives Amendments of 1960, Pub. L. No. 86-618, 74 Stat. 397.

products.<sup>69</sup> The FPLA also stipulated that required labels be prominently placed on the package in a conspicuous type size.<sup>70</sup> However, many of these requirements already appeared under the FD&C Act.<sup>71</sup> Collectively, these amendments delineated the FDA's authority under the FD&C Act and imposed additional restrictions on food manufacturers.<sup>72</sup>

In 1969, the Nixon Administration convened the White House Conference on Food, Nutrition, and Health to address growing concerns regarding the nutrition content of American food products resulting from the rise in the food production, processing, and packaging industries.<sup>73</sup> The event led to a major shift in the FDA's regulatory methods.<sup>74</sup> In 1973, the FDA issued regulations requiring nutritional labeling on any food product making a claim regarding its nutritional value or to which the manufacturer had added nutrients.<sup>75</sup> The regulations also specified some labeling formats and various nutrients that manufacturers had to include on their labels.<sup>76</sup> Additionally, the FDA required labeling of fat and cholesterol content in the nutritional labeling in a per-serving form, but only if the manufacturer first voluntarily chose to label the product with fat and

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69. Lyons & Rumore, *supra* note 13, at 175; Fair Packaging and Labeling Act, Pub. L. No. 89-755, § 4, 80 Stat. 1296, 1297-98 (1966) (codified as amended at 15 U.S.C. § 1453 (2006)).

70. Lyons & Rumore, *supra* note 13, at 175; Fair Packaging and Labeling Act § 4.

71. Hutt & Hutt, *supra* note 30, at 63.

72. Greenberg, *supra* note 30, at 10.

73. *Id.* at 11; Hutt & Hutt, *supra* note 30, at 67; WHITE HOUSE CONFERENCE ON FOOD, NUTRITION, AND HEALTH: FINAL REPORT 5-6 (1969), available at [http://www.nns.nih.gov/1969/full\\_report/PDFContents.htm](http://www.nns.nih.gov/1969/full_report/PDFContents.htm).

74. Hutt & Hutt, *supra* note 30, at 68.

75. Nutrition Labeling, 38 Fed. Reg. 6,951, 6,959 (Mar. 14, 1973); see also Blumenthal, *supra* note 52, at 15.

76. Nutrition Labeling, 38 Fed. Reg., *supra* note 75, at 6,959; Blumenthal, *supra* note 52, at 15. The regulations required listing the serving size; calorie content; servings per container; carbohydrate, fat, and protein content; vitamin A, vitamin C, thiamin, riboflavin, niacin, calcium, and iron content. Nutrition Labeling, 38 Fed. Reg., *supra* note 75, at 6,959; see also Blumenthal, *supra* note 52, at 15. The regulations also required listing vitamin D, vitamin E, vitamin B4, folic acid, vitamin B12, phosphorus, iodine, magnesium, zinc, copper, biotin, and pantothenic acid when the manufacturer added those nutrients to the product, and permitted their listing if the nutrients naturally appeared in the product. Nutrition Labeling, 38 Fed. Reg., *supra* note 75, at 6,959; see also Blumenthal, *supra* note 52, at 15. The FDA added sodium reporting to these requirements in 1984. Lyons & Rumore, *supra* note 13, at 178.

cholesterol content.<sup>77</sup> By 1989, a FDA study estimated that “approximately 60 percent of processed and packaged foods regulated by [the] FDA carr[ie]d nutrition labeling.”<sup>78</sup>

Despite these substantial new labeling requirements, significant gaps still remained in consumers’ knowledge of the nutritional value of their food.<sup>79</sup> Scientific research and important reports from the Surgeon General, the National Academy of Sciences, and the Institute of Medicine increasingly revealed the close relationship between diet and health.<sup>80</sup> The *Dietary Guidelines for Americans*, first published in 1980 by the USDA and the Department of Health, Education, and Welfare (now the Department of Health and Human Services (DHHS)), advocated important changes to average American diets.<sup>81</sup> Clear evidence of links between fat and cholesterol consumption and negative effects on human health conflicted with the unrestrictive voluntary labeling under the contemporary FDA regulation.<sup>82</sup> New data concerning the nutritional value of nutrients

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77. Labeling of Foods With Information on Cholesterol and Fat and Fatty Acid Composition, 38 Fed. Reg. 6,961 (Mar. 14, 1973); *see also* Blumenthal, *supra* note 52, at 15.

78. Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision, 55 Fed. Reg. 29,487, 29,490 (Jul. 19, 1990); *see also* Greenberg, *supra* note 30, at 11.

79. David A. Kessler et al., *Developing the “Nutrition Facts” Food Label*, 4 HARV. HEALTH POL’Y REV. 13, 14 (2003).

80. Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision, 55 Fed. Reg., *supra* note 78, at 29,490 (detailing comments received by the FDA in preparation for potential new labeling regulation); *see also* Kessler et al., *supra* note 79, at 14.

81. *See generally* U.S. DEP’T OF AGRIC. & U.S. DEP’T OF HEALTH & HUMAN SERVS., NUTRITION AND YOUR HEALTH: DIETARY GUIDELINES FOR AMERICANS (2d ed. 1985), available at <http://www.cnpp.usda.gov/Publications/DietaryGuidelines/1985/DG1985pub.pdf>. While frequently controversial, these guidelines provided the basis, in part, for the original “Nutrition Facts” food label. Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision, 55 Fed. Reg., *supra* note 78, at 29,490; *see also* Kessler et al., *supra* note 79, at 14. The Department of Agriculture and Department of Health and Human Services continue to update these guidelines. The “2010 Dietary Guidelines for Americans” were released in January 2011 and represent the most recent iteration of the Guidelines. Press Release, U.S. Dep’t of Agric., *USDA and HHS Announce New Dietary Guidelines to Help Americans Make Healthier Food Choices and Confront Obesity Epidemic* (Jan. 31, 2011), available at <http://www.cnpp.usda.gov/Publications/DietaryGuidelines/2010/PolicyDoc/PressRelease.pdf>; U.S. DEP’T OF AGRIC. & U.S. DEP’T OF HEALTH & HUMAN SERVS., DIETARY GUIDELINES FOR AMERICANS 2010 (7th ed. 2010), available at <http://www.cnpp.usda.gov/Publications/DietaryGuidelines/2010/PolicyDoc/PolicyDoc.pdf>.

82. *See* Greenberg, *supra* note 30, at 11.

such as fiber suggested a need for their inclusion.<sup>83</sup> At the same time, a lack of precise standards for the labeling format had resulted in inconsistent and sometimes confusing labels.<sup>84</sup> Units of measurement in use at the time had proven unclear to many consumers.<sup>85</sup> Conflicting state labeling requirements made compliance difficult for manufacturers, especially because the FDA permitted some manufacturers more latitude to make health claims than others,<sup>86</sup> and caused confusion for consumers.<sup>87</sup> In response, commentators argued that better labeling would encourage the production of healthier foods and discourage misleading health claims.<sup>88</sup> The deficiencies in the labeling led both the FDA and Congress to commence efforts toward new regulation.<sup>89</sup>

Congress beat the FDA to the punch, passing the Nutrition Labeling and Education Act of 1990 (NLEA).<sup>90</sup> The NLEA addressed the concerns surrounding the previous labeling scheme by providing national labeling requirements, granting the Secretary of the Department of Health and Human Services authority to define

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83. Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision, 55 Fed. Reg., *supra* note 78, at 29,490.

84. Kessler et al., *supra* note 79, at 14; *see also* Lyons & Rumore, *supra* note 13, at 180. The FDA had left important aspects of the format, such as typeface, type size, and label location, to manufacturers to decide. Kessler et al., *supra* note 79, at 14.

85. Kessler et al., *supra* note 79, at 15. The RDAs in the pre-NLEA nutritional labels listed contents in measurements such as grams and milligrams. *Id.* Consumers frequently failed to understand the significance of these units. *Id.*

86. *Id.* at 14; *see also* Greenberg, *supra* note 30, at 13 (explaining the food industry's preference for uniform labeling throughout the nation). For an extensive discussion of the differences between federal and state nutrition labeling prior to the NLEA, *see* COMM. ON STATE FOOD LABELING, INST. OF MED., FOOD LABELING: TOWARD NATIONAL UNIFORMITY 85-140 (Donna V. Porter & Robert O. Earl eds., 1992), *available at* [http://www.nap.edu/catalog.php?record\\_id=2001](http://www.nap.edu/catalog.php?record_id=2001).

87. Kessler et al., *supra* note 79, at 14; *see also* Edward Scarbrough, *Perspectives on Nutrition Labeling and Education Act*, in NUTRITION LABELING HANDBOOK 29, 47-48 (Ralph Shapiro ed., 1995).

88. Fred R. Shank, *The Nutrition Labeling and Education Act of 1990*, 47 FOOD & DRUG L.J. 247, 249 (1992) (explaining that the labeling requirements provided a disincentive to introduce healthier food products).

89. Greenberg, *supra* note 30, at 11 (explaining the "two-track" effort in updating food labeling standards); *see also* COMMITTEE ON THE NUTRITION COMPONENTS OF FOOD LABELING, INST. OF MED., NUTRITION LABELING: ISSUES AND DIRECTIONS FOR THE 1990S 63-71 (Donna V. Porter & Robert O. Earl eds., 1990) (outlining critiques of pre-NLEA food labeling).

90. Greenberg, *supra* note 30, at 10.

specific terminology, and giving the FDA enforcement power under the FD&C Act.<sup>91</sup> The new legislation dispensed with voluntary labeling for most packaged foods and required labeling of serving size in “common household measure[s],” number of servings, and calories, including identification of calories from all sources and calories from fat.<sup>92</sup> The NLEA also mandated the listing of the amounts of certain specified nutrients, as well as any other nutrients deemed relevant by the Secretary.<sup>93</sup> To resolve consumer confusion over the units of measurement the new nutrition labeling included the percentage of the U.S. Recommended Daily Allowance of each nutrient.<sup>94</sup> In certain circumstances, information must be in “larger type, bold face, or contrasting color.”<sup>95</sup> The NLEA also limited the health claims that manufacturers could use and gave the Secretary latitude to regulate some of the terminology employed on packaging.<sup>96</sup> The NLEA solved the problem of conflicting state laws by preempting them, expressly stating that no state could employ labeling regulations inconsistent with the national regulations.<sup>97</sup> The NLEA thus addressed many of the problems identified with previous nutritional labeling and fit into a broader trend of granting the FDA considerable discretion in tackling nutritional concerns.<sup>98</sup>

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91. Termini, *supra* note 59, at 101–03; *see also* Christine Lewis Taylor & Virginia L. Wilkening, *How the Nutrition Food Label Was Developed, Part 1: The Nutrition Facts Panel*, 108 J. AM. DIETETIC ASS’N 437 (2008) (discussing some “guiding principles” of the design of the new food label).

92. Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, § 2, 104 Stat. 2353, 2353–57 (codified as amended at 21 U.S.C. § 343).

93. *Id.* The NLEA specifically required inclusion of “[t]otal fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein,” and any other nutrients that the Secretary determined would “assist consumers in maintaining healthy dietary practices.” *Id.*

94. Kessler et al., *supra* note 79, at 15.

95. Termini, *supra* note 59, at 95.

96. Nutrition Labeling and Education Act § 3; *see also* Termini, *supra* note 59, at 95. The NLEA specifically ordered the Secretary of the Department of Health and Human Services to develop standards for claiming a relationship between “calcium and osteoporosis, dietary fiber and cancer, lipids and cardiovascular disease, lipids and cancer, sodium and hypertension, and dietary fiber and cardiovascular disease.” Nutrition Labeling and Education Act § 3. The NLEA permitted claims only when “significant scientific agreement” supported them. *See id.* The NLEA also required the Secretary to develop definitions for certain common terms, including “free,” “low,” “light or lite,” “reduced,” “less,” and “high.” Termini, *supra* note 59, at 101.

97. Nutrition Labeling and Education Act § 6; *see also* Termini, *supra* note 59, at 102.

98. Kessler, *supra* note 33, at xx.

In the same year that the NLEA was passed, Congress also passed the Organic Foods Production Act of 1990 (OFPA), which instituted organic food labeling regulations.<sup>99</sup> Congress placed the bulk of regulatory authority for this new form of labeling under the USDA's authority rather than that of the FDA, emphasizing the OFPA's focus on the agricultural origin of the labeled food product.<sup>100</sup> The OFPA granted the USDA authority to establish a certification program for organic foods, including a seal indicating compliance with the USDA's regulations and specifications concerning the use of terms such as "organic" on labels.<sup>101</sup> The OFPA identified numerous practices that farmers would have to maintain in order to qualify for organic labeling under the OFPA.<sup>102</sup> The OFPA also permitted states to request to establish organic certification programs at least as restrictive as the USDA's standards.<sup>103</sup> In addition, the OFPA established a National Organic Standard Board to "assist in the development of standards for substances to be used in organic production" and to advise the government in the implementation of the organic certification program.<sup>104</sup> The OFPA and ensuing USDA regulations created a new labeling standard focused more on the production process rather than on the end product.<sup>105</sup>

Congress established another variety of food labeling with the passage of the Dietary Supplement Health and Education Act of 1994

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99. Organic Foods Production Act of 1990, Pub. L. No. 101-624, 104 Stat. 3935 (codified as amended at 7 U.S.C. §§ 6501-6523 (2006)).

100. *See id.*; *see also* Michelle T. Friedland, *You Call That Organic?—The USDA's Misleading Food Regulations*, 13 N.Y.U. ENVTL. L.J. 379, 382-83 (2005).

101. Organic Foods Production Act §§ 2104-2106; *see also* Terence J. Centner & Kyle W. Lathrop, *Differentiating Food Products: Organic Labeling Provisions Facilitate Consumer Choice*, 1 DRAKE J. AGRIC. L. 30, 42-43 (1996). The USDA has created definitions for the terms "100% organic," "organic" (at least 95% organic ingredients), and "made with organic" (at least 70% organic ingredients), and it permits products with less than 70% organic ingredients to list their organic ingredients in the nutrition label. U.S. DEP'T OF AGRIC., NATIONAL ORGANIC PROGRAM ONLINE TRAINING, *available at* <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5080172>. The USDA has also enacted detailed requirements for the format of the organic label and seal, such as typeface, color, and location, as well as methods for calculating the ingredient percentages. *Id.* In addition, the USDA has restricted claims that a food product has a superior level of "organicness." *Id.*

102. Organic Foods Production Act § 2109-2113.

103. *Id.* § 2108.

104. *Id.* § 2119.

105. Friedland, *supra* note 100, at 384.



(DSHEA). The DSHEA defined a new category of products that were considered neither foods nor drugs.<sup>106</sup> Intended to give the FDA the power to address safety concerns regarding supplements, to ensure proper labeling of supplements, and to increase the availability of dietary supplements to consumers,<sup>107</sup> the DSHEA has proven to be highly controversial.<sup>108</sup> The law halted attempts by the FDA to regulate dietary supplements as food additives, which would have required pre-approval of supplements before use,<sup>109</sup> and instead established a new dietary supplement subcategory.<sup>110</sup> The DSHEA mandated labeling requirements for dietary supplements<sup>111</sup> and

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106. Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (codified in scattered sections of 21 U.S.C.).

107. Joseph A. Levitt, *Regulation of Dietary Supplements: FDA's Strategic Plan*, 57 FOOD & DRUG L.J. 1, 1 (2002).

108. See, e.g., Debra D. Burke & Anderson P. Page, *Regulating the Dietary Supplements Industry: Something Still Needs to Change*, 1 HASTINGS BUS. L.J. 121 (2005) (advocating for reforms in FDA and FTC dietary supplement regulatory practices); Peter J. Cohen, *Science, Politics, and the Regulation of Dietary Supplements: It's Time to Repeal DSHEA*, 31 AM. J.L. & MED. 175 (2005) (calling for outright repeal of DSHEA). But see Stephen H. McNamara & A. Wes Siegner, Jr., *FDA Has Substantial and Sufficient Authority to Regulate Dietary Supplements*, 57 FOOD & DRUG L.J. 15 (2002) (arguing that the problems with dietary supplement regulation lie in the FDA's failure to properly employ its authority under DSHEA rather than with DSHEA itself).

109. Lars Noah & Barbara A. Noah, *A Drug by Any Other Name . . .?: Paradoxes in Dietary Supplement Risk Regulation*, 17 STAN. L. & POL'Y REV. 165, 168-69 (2006).

110. See Dietary Supplement Health and Education Act § 3. The DSHEA defined a "dietary supplement" as "a product (other than tobacco) intended to supplement the diet" containing

(A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E).

*Id.* (internal quotation marks omitted). The DSHEA also defined "dietary supplement" as a product that "is not represented for use as a conventional food or as a sole item of a meal or the diet," that "is intended for ingestion," and that "is labeled as a dietary supplement." *Id.* (internal quotation marks omitted); see also Martin Hahn, *Functional Foods: What Are They? How Are They Regulated? What Claims Can Be Made?*, 31 AM. J.L. & MED. 305, 315 (2005). Critics have argued that this definition does not provide the FDA sufficient guidance concerning what it should consider a "dietary supplement." See generally Suzan Onel, *Dietary Supplements: A Definition That Is Black, White, and Gray*, 31 AM. J.L. & MED. 341 (2005).

111. Dietary Supplement Health and Education Act § 7. The DSHEA required dietary supplement labels to "identify the product by using the term 'dietary supplement;'" to display the name and quantity of each ingredient listed in Section 201(ff) of the FD&C Act, including "vitamin[s]," "mineral[s]," "herb[s] or other botanical[s]," "amino acid[s]," "dietary substance[s] for use by man to supplement the diet by increasing the total dietary intake," and

prescribed limits on health claims that manufacturers could make,<sup>112</sup> but specifically exempted them from regulation as food additives.<sup>113</sup> The DSHEA also gave the FDA authority to regulate unsafe supplements as adulterated food products,<sup>114</sup> but placed the burden of proof on the FDA to prove a supplement unsafe.<sup>115</sup> In effect, the DSHEA limited the scope of the FDA's regulatory discretion in relation to a substantial class of ingestible products.<sup>116</sup>

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"concentrate[s], metabolite[s], constituent[s], extract[s], or combination[s] of" each of the above; to include the quantity of each of those ingredients in a "proprietary blend;" to identify all plant parts from which those ingredients are derived; and to accurately represent the identity, strength, quality, and purity of the supplement. *Id.*; Food, Drug, and Cosmetic Act § 201(ff).

112. *Id.* § 6. The DSHEA allowed certain claims regarding "classical nutrient deficiency disease[s]" but barred claims that a supplement could "diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases." *Id.* Before the passage of the DSHEA, the FDA restricted claims on the basis of language in the FD&C Act that defined drugs as "articles (other than food) intended to affect the structure or any function of the body." *See* Federal Food, Drug, and Cosmetic Act, § 201(g), 52 Stat. 1040, 1041 (1938) (codified as amended at 21 U.S.C. § 321 (2006)); *see also* Hahn, *supra* note 110, at 323. However, the narrower language in the DSHEA forced the FDA to expand the category of health claims that it had previously allowed for food products under the NLEA in order to avoid inconsistent application of its regulations. *See id.*

113. Dietary Supplement Health and Education Act § 3(b).

114. *Id.* § 4. The DSHEA permitted the FDA to consider a supplement "adulterated" if it "presents a significant or unreasonable risk of illness or injury under . . . conditions of use recommended or suggested in labeling, or . . . if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use," or if there is "inadequate information to provide reasonable assurance" that no "significant or unreasonable risk" exists. *Id.*

115. *Id.* Commentators have argued that this provision ties the hands of the FDA in preventing potentially dangerous supplements from reaching the market. *See, e.g.,* Trisha L. Beckstead, *Caveat Emptor, Buyer Beware: Deregulation of Dietary Supplements Upon Enactment of the Dietary Supplement Health and Education Act of 1994*, 11 SAN JOAQUIN AGRIC. L. REV. 107, 130 (2001); Morgan J. Wais, *Stomaching the Burden of Dietary Supplement Safety: The Need to Shift the Burden of Proof Under the Dietary Supplement Health and Education Act of 1994*, 28 SEATTLE U. L. REV. 849, 867-68 (2005).

116. Peter Barton Hutt, *FDA Statutory Authority to Regulate the Safety of Dietary Supplements*, 31 AM. J.L. & MED. 155, 156 (2005). In 2006, Congress passed the Dietary Supplement and Nonprescription Drug Consumer Protection Act (DSNDCPA) to respond to pressure for heightened regulation of supplements such as ephedra that caused illnesses and deaths. Dietary Supplement and Nonprescription Drug Consumer Protection Act, Pub. L. No. 109-462, 120 Stat. 3469 (2006) (codified in scattered sections of 21 U.S.C.). The DSNDCPA imposed new reporting requirements on the nutritional supplement industry but did not alter the provisions of the DSHEA. *See* Dietary Supplement and Nonprescription Drug Consumer Protection Act § 2; *see also* Katherine Wong, *New Mandatory Reporting Requirements for Dietary Supplements and Nonprescription Drugs Solve Very Little*, 35 J.L. MED. & ETHICS 336, 336-37 (2007).

In 2004, Congress expanded the reach of American food labeling regulation to address a new challenge posed by allergens in food products by passing the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA).<sup>117</sup> The FALCPA required labeling of a class of “major food allergen[s]” known to cause a majority of serious allergic reactions.<sup>118</sup> The FALCPA also required the FDA to improve the collection of data concerning food allergens<sup>119</sup> and to convene a panel of experts to review current research efforts on food allergens.<sup>120</sup> The FALCPA responded to the particular needs of a specific class of consumers regarding their food products.<sup>121</sup>

Consumers, the food industry, and other interested parties have continued to push for further amendments to American food labeling regulations in order to address other topics of concern to them. Some of these proposals have advocated regulations to aid specific groups of consumers, such as children<sup>122</sup> and vegans.<sup>123</sup> Others have pushed for regulations to address specific segments of the food industry, such as producers of fast food.<sup>124</sup> Still others have suggested the need for regulations to account for advances in food production technology,

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117. Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108-282, 118 Stat. 905 (codified in scattered sections of 21 U.S.C.); see also Laura E. Derr, *When Food Is Poison: The History, Consequences, and Limitations of the Food Allergen Labeling and Consumer Protection Act of 2004*, 61 FOOD & DRUG L.J. 65, 66 (2006).

118. See Food Allergen Labeling and Consumer Protection Act §§ 202, 203(a). The FALCPA definition of “major food allergen” encompassed, *inter alia*, “[m]ilk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans.” *Id.* § 203(c); see also Derr, *supra* note 117, at 116–21. The FALCPA also required the FDA to develop a definition for the term “gluten-free.” Food Allergen Labeling and Consumer Protection Act § 206.

119. Food Allergen Labeling and Consumer Protection Act § 207.

120. *Id.* § 208.

121. See Derr, *supra* note 117, at 66.

122. See, e.g., Gail H. Javitt, *Supersizing the Pint-Sized: The Need for FDA-Mandated Child-Oriented Food Labeling*, 39 LOY. L.A. L. REV. 311 (2006).

123. See, e.g., *Vegan Certification*, VEGAN ACTION, <http://www.vegan.org/campaigns/certification/index.html> (last visited Sept. 17, 2011).

124. See, e.g., Haitham M. Ahmed, *Obesity, Fast Food Manufacture, and Regulation: Revisiting Opportunities For Reform*, 64 FOOD & DRUG L.J. 565, 568–69 (2009); Michael McCann, *Economic Efficiency and Consumer Choice Theory in Nutritional Labeling*, 2004 WIS. L. REV. 1161, 1233–44.

such as genetically modified foods.<sup>125</sup> In addition, increased availability of nutrition information online and through other technological means has begun to supplement the traditional labeling on packaging, potentially affecting numerous aspects of future labeling.<sup>126</sup> Food labeling will continue to evolve as technology, consumer movements, and political change inspires new regulations.

### III. CURRENT STATUS OF HOUSEHOLD CHEMICAL LABELING

Federal law currently regulates household chemical labeling under a variety of different statutes and administrative agencies.<sup>127</sup> Under the Consumer Product Safety Act (CPSA),<sup>128</sup> the CPSC has the authority to regulate all products intended for use by consumers, subject to a range of exceptions.<sup>129</sup> This includes the primary

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125. See, e.g., LABELING GENETICALLY MODIFIED FOOD: THE PHILOSOPHICAL AND LEGAL DEBATE (Paul Weirich ed., 2007); Kirsten S. Beaudoin, *On Tonight's Menu: Toasted Cornbread With Firefly Genes? Adapting Food Labeling Law to Consumer Protection Needs in the Biotech Century*, 83 MARQ. L. REV. 237, 262–78 (1999); R. Wes Harrison & Everal Mcleannon, *Analysis of Consumer Preferences for Biotech Labeling Formats*, 36 J. AGRIC. APPLIED ECON. 159 (2004) (noting a study that found consumer support for labeling of genetically modified foods). For a recent argument against such labeling, see GARY E. MARCHANT ET AL., THWARTING CONSUMER CHOICE: THE CASE AGAINST MANDATORY LABELING FOR GENETICALLY MODIFIED FOODS (2010).

126. See, e.g., NUTRITION.GOV, <http://www.nutrition.gov> (last modified July 29, 2011).

127. See Lars Noah, *The Imperative to Warn: Disentangling the "Right to Know" from the "Need to Know" About Consumer Product Hazards*, 11 YALE J. ON REG. 293, 298–301 (1994) (detailing some of the major acts and the federal agency responsibilities under them). For a more detailed outline of the Consumer Product Safety Commission's labeling requirements, see DANIEL S. WAGNER, INT'L SANITARY SUPPLY ASS'N, PRECAUTIONARY LABELING FOR CONSUMER PRODUCTS (2001), available at [http://www.issa.com/data/files/articles/88/consumer\\_precautionary\\_label.pdf](http://www.issa.com/data/files/articles/88/consumer_precautionary_label.pdf).

128. Consumer Product Safety Act, Pub. L. No. 92-573, 86 Stat. 1207 (1972) (codified at 15 U.S.C. §§ 2051–2084). The CPSA defines a "consumer product" as:

[A]ny article, or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise[.]

Consumer Product Safety Act § 3, 15 U.S.C. § 2052(a)(5) (2006).

129. 15 U.S.C. § 2052(a)(5). The exceptions include "any article which is not customarily produced or distributed for sale to, or use or consumption by, or enjoyment of, a consumer," tobacco and tobacco products, motor vehicles or motor vehicle equipment, pesticides, firearms and ammunition, aircraft, and certain aircraft parts, boats, drugs, devices, or cosmetics, as

authority to regulate labeling of household chemicals, except for those regulated by the FDA under the FD&C Act, the EPA under the Federal Insecticide, Fungicide, and Rodenticide Act, and a few more minor exceptions.<sup>130</sup> Much of the agency's current household chemical labeling scheme has come from rules issued pursuant to the CPSA, along with several other federal laws.<sup>131</sup> The CPSA grants the CPSC the authority to issue "[r]equirements that a consumer product be marked with or accompanied by clear and adequate warnings or instructions, or requirements respecting the form of warnings or instructions."<sup>132</sup> However, in order to proceed under the CPSA,<sup>133</sup> the CPSC must find that the regulation "is reasonably necessary to eliminate or reduce an unreasonable risk of injury," that it "is in the public interest," that any "voluntary consumer product safety standard" employed is inadequate, that the "benefits expected from the rule bear a reasonable relationship to its costs," and that the regulation "imposes the least burdensome requirement" that eliminates the hazard posed.<sup>134</sup> Thus, the CPSC can issue warnings or labels pursuant to the CPSA only after a thorough, individualized rulemaking process based on substantial evidence.<sup>135</sup> The CPSA also contains reporting provisions that require manufacturers to inform the

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defined in the FD&C Act, "food," and a few more esoteric exceptions. *Id.*; I.R.C. § 4181 (2006) (imposing tax on firearms and ammunition).

130. 15 U.S.C. § 2052(a).

131. *See* Noah, *supra* note 127, at 299–301.

132. Consumer Product Safety Act § 7, 15 U.S.C. § 2056(a)(2) (2006).

133. Until 2008, the CPSC had to determine that the hazard presented "could not be regulated sufficiently under" the FHSA or that it was "in the public interest to proceed under" the CPSA. Consumer Product Safety Act § 30, 15 U.S.C. § 2079(d) (2006) (repealed 2008); *see also* *Gulf S. Insulation v. U.S. Consumer Prod. Safety Comm'n*, 701 F.2d 1137, 1149–50 (5th Cir. 1983) (explaining that the CPSC only has authority to regulate dangerous products under 15 U.S.C. § 2079(d) if the risk "could not be regulated sufficiently under" the FHSA, or if it was "in the public interest to proceed under" the FHSA, and that this requirement cannot be altered by the CPSC's desire to avoid the FHSA's formal rulemaking requirement). The CPSIA's repeal of section 2079(d) may change the result in cases like *Gulf South Insulation*, and recently proposed rules by the CPSC indicate that it intends to exercise the new authority provided by the repeal. *See, e.g.*, CONSUMER PRODUCT SAFETY COMM., PROPOSED DETERMINATION THAT CHILDREN'S UPPER OUTERWEAR IN SIZES 2T TO 12 WITH NECK OR HOOD DRAWSTRINGS AND CHILDREN'S UPPER OUTERWEAR IN SIZES 2T TO 16 WITH CERTAIN WAIST OR BOTTOM DRAWSTRINGS ARE A SUBSTANTIAL PRODUCT HAZARD 6 (May 11, 2010), available at <http://www.cpsc.gov/library/foia/foia10/brief/drawstrFRdraft.pdf>.

134. Consumer Product Safety Act § 9, 15 U.S.C. § 2058(f)(3) (2006).

135. Rawlins, *supra* note 17, at 25–26.

CPSC if any of their products “creat[e] an unreasonable risk of serious injury or death,” have a defect that “could create a substantial product hazard,” or that do not comply with the CPSA or any voluntary safety standards relied upon by the CPSC.<sup>136</sup>

The Federal Hazardous Substances Act (FHSA), passed in 1960, provides the Commission with expanded authority to regulate the labeling of “hazardous substances.”<sup>137</sup> Rules issued pursuant to the FHSA form the bulk of CPSC labeling requirements for chemical products, and much litigation has centered around whether a particular product meets the FHSA’s definition of a “hazardous substance.”<sup>138</sup> The FHSA considers a “hazardous substance” misbranded if it does not bear a label complying with the requirements of the FHSA.<sup>139</sup> A chemical is a “hazardous substance” if it is toxic, corrosive, an irritant, a strong sensitizer, flammable or combustible or “generates pressure through decomposition, heat, or other means.”<sup>140</sup> Under the FHSA and the regulations enacted pursuant to it, the CPSC bears the burden of proving that a hazardous substance meets the FHSA’s definition of “toxic,”<sup>141</sup> that humans

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136. Consumer Product Safety Act § 15, 15 U.S.C. § 2064(b) (2006).

137. See Federal Hazardous Substances Act, Pub. L. No. 86-613, 74 Stat. 372 (1960) (codified at 15 U.S.C. §§ 1261–1278).

138. WAGNER, *supra* note 127, at 2–3.

139. 15 U.S.C. § 1261(p). The label must conspicuously display “the name and place of business of the manufacturer, packer, distributor or seller,” as well as “the common or usual name or the chemical name (if there be no common or usual name) of the hazardous substance of each component” that contributes substantially to its hazard. *Id.* The FHSA also requires the label to bear the word “DANGER” on “flammable, corrosive, or highly toxic” substances, the words “WARNING” or “CAUTION” on all other hazardous substances and the word “Poison” on any product considered “highly toxic,” along with a statement indicating why it is hazardous (i.e., “flammable,” “vapor harmful,” etc.), and descriptions of appropriate precautions and treatments. *Id.*

140. 15 U.S.C. § 1261(f) (2006). The FHSA also granted the Secretary of Health, Education, and Welfare discretion to declare other substances hazardous if she determines that they satisfy the requirements of the FHSA’s definition. Federal Hazardous Substances Act § 3, 15 U.S.C. § 1262(a) (2006). The FHSA does not apply to pesticides covered by the FIFRA or food, drugs, and cosmetics covered by the FD&C Act. Federal Hazardous Substances Act § 2, 15 U.S.C. § 1261(f) (2006).

141. The FHSA defines “toxic” as “any substance . . . which has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface.” 15 U.S.C. § 1261(g). The CPSC’s regulations supplement the FHSA’s definition of “toxic” to include “acute toxicity,” substances causing death to certain specified laboratory animals within fourteen days, and “chronic toxicity,” substances containing known or probable human carcinogens, neurotoxins, or developmental or reproductive toxicants. 16 C.F.R.

have the potential to be exposed to it, and that it carries “a significant risk of an adverse health effect.”<sup>142</sup> The FHSA also permits the CPSC to ban hazardous substances intended for use in the household if the Commission determines that such a ban is necessary to protect the public.<sup>143</sup> However, the FHSA’s extensive rule-making procedure involves hearings and detailed findings of fact before action may be taken pursuant to the Act.<sup>144</sup> These procedures have limited the scope of the CPSC’s enforcement under the FHSA.<sup>145</sup>

The Poison Prevention Packaging Act of 1970 (PPPA) requires additional packaging for some products that could poison children.<sup>146</sup> The PPPA permits the CPSC to mandate “special packaging of any household substance” if it finds that requiring such packaging would protect children from harm caused by “handling, using, or ingesting” the product.<sup>147</sup> However, the PPPA specifically denies the CPSC the authority to prescribe special labeling for those products,<sup>148</sup> except when the need to keep products accessible to “elderly or handicapped persons” overrides the need for “special packaging . . . designated or constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the substance contained therein.”<sup>149</sup> The PPPA also amends the FHSA, the FD&C

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§ 1500.3(c)(2) (2006). Guidelines issued for determining the chronic toxicity of a substance suggest “sufficient” or “limited” evidence of its status as a human carcinogen, or “sufficient” evidence of that status based on animal studies, must exist. *Id.* § 1500.135(a)-(c). These guidelines exclude *possible* carcinogens, neurotoxins, or developmental or reproductive toxicants, including “agents with ‘limited’ evidence of carcinogenicity from animal studies.” Rawlins, *supra* note 17, at 24.

142. *See* 16 C.F.R. § 1500.135(d); *see also* Rawlins, *supra* note 17, at 24–26. The Guidelines state that an “adverse health effect” exists where the exposure level “is above the acceptable daily intake.” 16 C.F.R. § 1500.135(d).

143. 15 U.S.C. § 1261(q); *see also* Rawlins, *supra* note 17, at 23.

144. Federal Hazardous Substances Act § 3, 15 U.S.C. § 1262(f)-(i) (2006); *see also* Rawlins, *supra* note 17, at 24.

145. *See* Rawlins, *supra* note 17, at 23–30.

146. Poison Prevention Packaging Act of 1970, 15 U.S.C. §§ 1471–1477 (2006); *see also* William E. Hilton, *Risk and Value Judgments: A Case Study of the Poison Prevention Packaging Act*, 3 RISK: ISSUES HEALTH & SAFETY 37, 38–39 (1992).

147. Poison Prevention Packaging Act § 3.

148. *Id.*

149. *Id.* §§ 2, 4. In those circumstances, the PPPA would require a label reading: “This package for households without young children,” or a substitute label when the size of the package would not permit that message. *Id.* § 4. Under limited circumstances, a manufacturer may petition for exemption from the PPPA’s requirements. 16 C.F.R. § 1702 (2009).

Act, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to apply its provisions to the products regulated under those laws.<sup>150</sup>

In 2008, in response to public health scares caused by the presence of lead in children's toys,<sup>151</sup> Congress enacted the Consumer Product Safety Improvement Act (CPSIA).<sup>152</sup> The CPSIA amended many consumer protection laws, including the CPSA, the FHSA, and the CPSC's rules issued pursuant to those acts.<sup>153</sup> While controversial,<sup>154</sup> the CPSIA significantly expanded the CPSC's ability to regulate the manufacture of products intended for children<sup>155</sup> and provided for substantial agency reforms, including budget enhancements.<sup>156</sup> The CPSIA also added labeling requirements for children's products, mandating that manufacturers affix permanent "tracking labels" to those products.<sup>157</sup> These labels must permit the "ultimate purchaser to ascertain the manufacturer or private labeler, location and date of production of the product, and cohort information (including the batch, run number, or other identifying

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150. 15 U.S.C. § 1474 (2006).

151. Kevin Diaz & H. J. Cummins, *House Bans Lead from Children's Toys: A Local Boy's Death From Lead Poisoning Sparked the Move for Product Safety*, STAR TRIB., July 31, 2008, at A1, available at <http://www.startribune.com/politics/26122814.html>; see also Leslie Wayne, *Burden of Safety Law Imperils Small Toymakers*, N.Y. TIMES, Oct. 31, 2009, at B1, available at <http://www.nytimes.com/2009/10/31/business/smallbusiness/31toys.html>.

152. Consumer Product Safety Improvement Act of 2008, Pub. L. No. 110-314, 122 Stat. 3016 (codified in scattered sections of 15 U.S.C.).

153. *Id.*

154. Opponents of the CPSIA claim that the costs of compliance threaten to bankrupt small toy manufacturers and other small businesses, but consumer advocates claim that CPSIA will significantly reduce the risks to children's health. Compare Richard A. Epstein, *The Regulatory Farce Under the Consumer Product Safety Improvement Act*, FORBES.COM (Feb. 3, 2009) available at [http://www.forbes.com/2009/02/01/cpsia-congress-lead-opinions-columnists\\_0203\\_richard\\_epstein.html](http://www.forbes.com/2009/02/01/cpsia-congress-lead-opinions-columnists_0203_richard_epstein.html) (opposing the CPSIA), and Walter Olson, *Destructive Toy Story Made in Washington*, WSJ.COM (Sept. 13, 2009), available at <http://online.wsj.com/article/SB10001424052970203706604574370712943409146.html> (opposing the CPSIA), with Editorial, *A Win for Product Safety*, CONSUMER REPORTS, Dec. 2009, at 6, available at <http://www.consumerreports.org/cro/magazine-archive/december-2009/viewpoint/overview/a-win-for-product-safety-ov.htm> (supporting the CPSIA), and Editorial, *Is That Fabulous New Toy Safe?*, N.Y. TIMES, Feb. 17, 2009, at A26, available at <http://www.nytimes.com/2009/02/18/opinion/18wed3.html> (supporting the CPSIA).

155. See 15 U.S.C. § 1278(a) (2008).

156. See 15 U.S.C. § 2081 (2008).

157. 15 U.S.C. § 2063 (2008).



characteristic).”<sup>158</sup> The CPSIA labeling requirements represent Congress’s attempt to determine the source of a product in the event of a recall or for other safety purposes.<sup>159</sup>

In addition to the laws mandating labeling on products directed at consumers, the Occupational Safety and Health Act of 1970 (OSHA) established the Occupational Safety and Health Administration and mandated communication of hazards to employees in the workplace.<sup>160</sup> This communication may include the “use of labels or other appropriate forms of warning as are necessary to insure that employees are apprised of all hazards to which they are exposed, relevant symptoms and appropriate emergency treatment, and proper conditions and precautions of safe use or exposure.”<sup>161</sup> The OSHA’s Hazard Communication Standards require chemical manufacturers to create material safety data sheets for all hazardous chemicals and label hazardous chemicals not regulated by other federal agencies and laws.<sup>162</sup> The regulations provide for hazard warnings<sup>163</sup> for chemicals posing “health hazards”<sup>164</sup> and “physical hazards.”<sup>165</sup> The regulations

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158. *Id.* § 2063(a)(5)(B). The CPSIA also disallowed any “reference to a consumer product safety rule or a voluntary consumer product safety standard unless such product conforms with the applicable safety requirements of such rule or standard.” *Id.* § 2063(d).

159. See CONSUMER PROD. SAFETY COMM’N, STATEMENT OF POLICY: INTERPRETATION AND ENFORCEMENT OF SECTION 103(A) OF THE CONSUMER PRODUCT SAFETY IMPROVEMENT ACT 1 (2009), available at <http://www.cpsc.gov/ABOUT/Cpsia/sect103policy.pdf>; see also Susan DeRagon, *The Consumer Product Safety Improvement Act: Five Steps You Need to Take Before February 2010*, PROMOTIONAL PRODUCTS BUS. (Dec. 2009), available at <http://www.ppbmag.com/Article.aspx?id=5016>.

160. Occupational Safety and Health Act of 1970, Pub. L. No. 91-596, 84 Stat. 1590 (codified at 29 U.S.C. §§ 651–678 (2006)); see also Lisa K. Simkins & Charlotte A. Rice, *Hazard Communication and Worker Right-To-Know Programs*, in PATTY’S INDUSTRIAL HYGIENE V. 3, 1735, 1735 (Robert L. Harris ed., 5th ed. 2000).

161. Occupational Safety and Health Act § 6; Simkins & Rice, *supra* note 160, at 1735.

162. *Id.* at 1736–39; 29 C.F.R. § 1910.1200(b) (2009).

163. Hazard warnings are defined as “any words, pictures, symbols, or combination thereof appearing on a label or other appropriate form of warning which convey the specific physical and health hazard(s), including target organ effects, of the chemical(s) in the container(s).” 29 C.F.R. § 1910.1200(c).

164. “Health hazards” are defined as “chemical[s] for which there is statistically significant evidence based on at least one study conducted in accordance with established scientific principles that acute or chronic health effects may occur in exposed employees.” 29 C.F.R. § 1910.1200(c). Health hazards include “chemicals which are carcinogens, toxic or highly toxic agents, reproductive toxins, irritants, corrosives, sensitizers, hepatotoxins, nephrotoxins, neurotoxins, agents which act on the hematopoietic system, and agents which damage the lungs, skin, eyes, or mucous membranes.” *Id.*

also provide for “material safety datasheets” that must be maintained in each workplace and that must contain the names of any ingredients posing hazards, the hazards posed, emergency and safe handling information, and producer identification information.<sup>166</sup> Manufacturers must convey the sheets to employers, and employers must provide information and training to employees.<sup>167</sup> Because these regulations apply to chemicals employed in workplaces, they do not necessarily affect the labeling of chemicals that consumers would purchase for use in the home.<sup>168</sup> Further, the safety datasheets only communicate known hazards and do not provide for ingredient disclosure.<sup>169</sup>

Though the CPSC exercises primary jurisdiction over most chemical products, other agencies also have substantial authority to regulate the labeling of household chemicals.<sup>170</sup> Under the FD&C Act and the FPLA, the FDA has control over the labeling of chemicals considered to be foods, drugs, or cosmetics.<sup>171</sup> While foods and drugs do not present the same risks as household chemicals and generally do not contain the same component chemicals, cosmetics include a wide range of chemicals applied to the human body,<sup>172</sup> and incorporate many of the same chemicals employed in the manufacture of household chemical products.<sup>173</sup> Under the FD&C

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165. 29 C.F.R. § 1910.1200(f). Physical hazards are defined as “chemical[s] for which there is scientifically valid evidence that it is a combustible liquid, a compressed gas, explosive, flammable, an organic peroxide, an oxidizer, pyrophoric, unstable (reactive) or water-reactive.” 29 C.F.R. § 1910.1200(c).

166. 29 C.F.R. § 1910.1200(g).

167. 29 C.F.R. § 1910.1200(g)-(h).

168. Simkins & Rice, *supra* note 160, at 1735.

169. *See* 29 U.S.C. § 655(b)(7).

170. *See* Noah, *supra* note 127, at 298–302.

171. 21 U.S.C. § 393 (2006); 15 U.S.C. §§ 1451–1461 (2006).

172. The FD&C Act defines cosmetics as:

(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

21 U.S.C. § 321(i) (2006).

173. *See* CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP’T OF HEALTH AND HUMAN SERVS., FOURTH NATIONAL REPORT ON HUMAN EXPOSURE TO ENVIRONMENTAL CHEMICALS (2009), available at <http://www.cdc.gov/exposurereport/pdf/FourthReport.pdf> (reviewing environmental chemicals to which humans are exposed, including the sources of the

Act and the FPLA, cosmetics must bear a label indicating “the name and place of business of the manufacturer, packer, or distributor; and . . . an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.”<sup>174</sup> The regulations issued by the FDA have expanded on this requirement, mandating that cosmetics must “bear a declaration of the name of each ingredient in descending order of predominance.”<sup>175</sup> This requirement goes beyond that established by the CPSC for household chemical products in that an ingredient does not have to meet the FHSA’s definition of a “hazardous substance” in order to be subject to the labeling requirement.<sup>176</sup> However, the labeling requirements contain significant loopholes.<sup>177</sup> For example, manufacturers may obtain exemptions for both fragrances<sup>178</sup> and trade secrets.<sup>179</sup> In addition, despite regulatory language seeming to require the testing of every ingredient prior to use, the FDA has not actually required such testing in practice, so the accuracy of the statements on most labels remains unevaluated.<sup>180</sup>

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exposure). Household cleaning products and cosmetics share many chemicals in common, including some associated with risks to human health, such as phthalates, triclosan, musks, and acrylamide. *Id.*; see also REBECCA SUTTON, ENVTL. WORKING GRP., TEEN GIRLS’ BODY BURDEN OF HORMONE-ALTERING COSMETICS CHEMICALS (Sept. 24, 2008), available at <http://www.ewg.org/book/export/html/26953>.

174. 21 U.S.C. § 362 (2006). In addition, the design of the labeling and container must not mislead consumers, and the labeling must appear on the product in a sufficiently conspicuous manner so “as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.” *Id.* For a guide to the FDA’s specifications concerning the presentation of the required information, see FOOD AND DRUG ADMIN., COSMETIC LABELING GUIDE (1991), available at <http://www.fda.gov/cosmetics/cosmeticlabelinglabelclaims/cosmeticlabelingmanual/ucm126444.htm>.

175. 21 C.F.R. § 701.3(a) (2006).

176. *Id.*

177. Delia Gervin, *You Can Stand Under My Umbrella: Weighing Trade Secret Protection Against the Need for Greater Transparency in Perfume and Fragranced Product Labeling*, 15 J. INTELL. PROP. L. 315, 327–29 (2008).

178. 21 C.F.R. § 701.3(a). For example, under FDA regulations “fragrance or flavor may be listed as fragrance or flavor,” rather than as the specific chemicals comprising those fragrances and flavors. *Id.*

179. *Id.*; 21 C.F.R. § 720.8 (2009).

180. *Id.* The FDA regulations require that “[e]ach ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing” and that “[a]ny such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel: ‘Warning—The safety of this product has not been

In 2011, Representatives Jan Schakowsky, Ed Markey, and Tammy Baldwin introduced the Safe Cosmetics Act of 2011 (SCA of 2011) in the House of Representatives.<sup>181</sup> The proposed legislation would amend the FD&C Act to require registration of cosmetics producers and more stringent labeling on cosmetics products, among other provisions.<sup>182</sup> Labels on cosmetics products would have to list the names of all ingredients, including fragrances and preservatives currently exempted under the FD&C Act.<sup>183</sup> Cosmetic product labels

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determined.” 21 C.F.R. § 740.10(a) (2009). However, this requirement remains unenforced. Rawlins, *supra* note 17, at 11–13. The Personal Care Products Council, a cosmetics industry trade association, funds a theoretically independent testing organization, the Cosmetic Ingredient Review. COSMETIC INGREDIENT REVIEW, <http://www.cir-safety.org/index.shtml> (last visited Sept. 18, 2011). However, as of 2005, the Cosmetic Ingredient Review had evaluated only 11 percent of ingredients used in cosmetics. *Consumer Update—FDA Fails to Protect Consumers*, ENVTL. WORKING GRP. (Oct. 5, 2005), available at <http://www.ewg.org/skindeep/2005/10/05/fda-fails-to-protect-consumers/>; see also Rawlins, *supra* note 17, at 11–12. In addition, the Environmental Working Group challenged at least a few of the assessments that had been performed, and found that ingredients determined by the CIR to be unsafe were still in products. ENVTL. WORKING GRP., *supra*; see also Rawlins, *supra* note 17, at 11–12. Current law may even provide an incentive for the industry to avoid testing. See Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products*, 82 CORNELL L. REV. 773, 852 (1997) (arguing that the legal standards for toxic tort liability make remaining ignorant about the hazards of chemicals “the rational choice for manufacturers today”).

181. Safe Cosmetics Act of 2011, H.R. 2359, 112th Cong. (2011); Press Release, Office of Congresswoman Jan Schakowsky, Reps. Schakowsky, Markey, Baldwin Introduce Bill to Protect Consumers and Workers From Harmful Chemicals in Cosmetics (June 24, 2011), [http://schakowsky.house.gov/index.php?option=com\\_content&task=view&id=2948&Itemid=16](http://schakowsky.house.gov/index.php?option=com_content&task=view&id=2948&Itemid=16) (last visited Sept. 18, 2011). The legislation represents a revised version of the Safe Cosmetics Act of 2010, legislation criticized by small businesses concerned about the cost of its implementation. Safe Cosmetics Act of 2010, H.R. 5786, 111th Cong. (2010); Amy Westervelt, *New and Improved Safe Cosmetics Act Could Boost Green Chemistry*, FORBES.COM (June 27, 2011), available at <http://www.forbes.com/sites/amywestervelt/2011/06/27/new-and-improved-safe-cosmetics-act-could-boost-green-chemistry/>.

182. Press Release, Office of Congresswoman Jan Schakowsky, *supra* note 181.

183. H.R. 2359 § 613. Under the SCA of 2011, the term “ingredient” would include “chemicals that provide a technical or functional effect;” “chemicals that have no technical or functional effect in the cosmetic but are present by reason of having been incorporated into the cosmetic as an ingredient of another cosmetic ingredient;” “processing aids that are present by reason of having been added to a cosmetic during the processing of such cosmetic;” “substances that are present by reason of having been added to a cosmetic during processing for their technical or functional effect;” “the components of a fragrance, flavor, or preservative;” and “any individual component of a petroleum-derived, animal-derived, or other ingredient that the Secretary deems an ingredient.” H.R. 2359 § 611(4)(A). The new legislation would also cover “contaminants present at levels above technically feasible detection limits” and “contaminants that may leach from container materials or form via reactions over the shelf life of a cosmetic and that may be present at levels above technically feasible detection limits.” *Id.* § 611(4)(B).

would have to disclose all of the products' "ingredient[s] . . . in descending order of predominance,"<sup>184</sup> as well as all contaminants present at the lower of "[a] level that is greater than one part-per-billion by weight of product formation" or a "level that is greater than one percent of the restriction on the concentration for such contaminant for such use," as determined by the FDA under the Act.<sup>185</sup> The Act would also require labeling of nanomaterials.<sup>186</sup> The SCA of 2011 would dispense with many current exemptions, such as those for fragrances<sup>187</sup> and trade secrets,<sup>188</sup> although the concentration of ingredients in a cosmetic would remain confidential,<sup>189</sup> and affected entities could petition for certain information to remain confidential "if the entity show[ed] that there would be a serious negative impact to the entity's commercial interests if such information were disclosed to the public."<sup>190</sup> These labeling provisions would significantly expand the information available to consumers at the point of purchase.

In addition to the increased labeling requirements, the SCA of 2011 would impose a range of other health and safety requirements.<sup>191</sup> The proposed legislation would require the FDA to apply a "reasonable certainty of no harm standard"<sup>192</sup> to cosmetic products, and establish good manufacturing practices for cosmetics

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184. *Id.* § 613(a).

185. *Id.* § 613(c).

186. *Id.* § 613(d).

187. *Id.* § 611(4)(A).

188. *Id.* § 613(f).

189. *Id.* § 623(b).

190. *Id.* § 623(c). The FDA could not approve a petition if the petition would prevent public disclosure of "the name, identity, and structure of any chemical substance, contaminant, or impurity that is an ingredient," "all health and safety data related to that substance, contaminant, or impurity;" or "any data used to substantiate the safety of that substance, contaminant, or impurity." *Id.*

191. Press Release, Office of Congresswoman Jan Schakowsky, *supra* note 181.

192. The SCA of 2011 would define "reasonable certainty of no harm" to mean that "no harm will be caused to members of the general population or any vulnerable population by aggregate exposure to the cosmetic or ingredient." This definition would take into account "low-dose exposures to the cosmetic or ingredient," "additive effects resulting from repeated exposure to the cosmetic or ingredient over time" and "cumulative exposure resulting from all sources, including both the cosmetic or ingredient and environmental sources." H.R. 2359 § 611(7).

producers.<sup>193</sup> Manufacturers would have to submit safety information to the FDA concerning each cosmetic product and its ingredients, and regularly update that information.<sup>194</sup> The FDA would use this data to establish a publicly accessible database on the safety of cosmetics.<sup>195</sup> The FDA would evaluate the safety of cosmetics ingredients using data available to it from manufacturers and “authoritative source[s],”<sup>196</sup> and would place each ingredient on one of three lists, a “prohibited and restricted list,” a “safe without limits list,” and a “priority assessment list.”<sup>197</sup> No cosmetic product could be manufactured unless it was in compliance with the safety standard,

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193. H.R. 2359 § 614. The FDA would have to ensure that “the likely level of exposure to all sources of the ingredient or cosmetic (including environmental sources) that will result under the safety standard presents not more than a 1 in a million risk for any adverse health effect in any vulnerable population at the lower 95th percentile confidence interval,” or “the safety standard results in exposure to the amount or concentration of an ingredient or cosmetic that is shown to produce no adverse health effects, incorporating a[] margin of safety of at least 1,000 and considering the impact of cumulative exposure from all sources (including environmental sources).” *Id.*

194. H.R. 2359 § 615(a). Manufacturers would have to supply information concerning “[f]unctions and uses,” “[d]ata and information on the physical, chemical, and toxicological properties of each such ingredient or cosmetic,” “[e]xposure and fate information,” “[r]esults of all safety tests that the manufacturer can access or has conducted,” and “[a]ny other information used to substantiate the safety of such ingredient and cosmetic.” *Id.*

195. H.R. 2359 § 615(b).

196. H.R. 2359 § 616(a). The FDA would consider whether each ingredient “reacts with other substances to form harmful contaminants,” “is found to be present in the body through biomonitoring,” “is found in drinking water or air,” “is a known or suspected neurological or immunological toxicant, respiratory asthmagen, carcinogen, teratogen, or endocrine disruptor, or ha[s] other toxicological concerns (including reproductive or developmental toxicity),” or “is known to persist in the environment or bioaccumulate.” *Id.*

197. H.R. 2359 § 616(b-d). The prohibited and restricted list would contain ingredients prohibited from use in cosmetics products due to their failure to meet the safety standard, and ingredients limited only to specific applications where their use would comply with the standard. H.R. 2359 § 616(b). The “safe without limits” list would include ingredients determined by the FDA to be safe for use in cosmetics regardless of the cosmetic the ingredient was used in or the concentration of the ingredient in the product. H.R. 2359 § 616(c). The “priority assessment” list would include ingredients “which, because of a lack of authoritative information on the safety of the ingredient,” could not be listed on either the “prohibited and restricted” or the “safe without limits” lists, and for which the FDA had determined a safety assessment was a priority. H.R. 2359 § 616(d). If “insufficient information” existed, the FDA would provide guidance to the manufacturer concerning the additional information needed to make an assessment. *Id.* The manufacturer would have eighteen months to either “reformulate such cosmetic to eliminate the use of the ingredient” or provide the necessary information. *Id.* If the FDA could not place the ingredient on either the “prohibited and restricted” or the “safe without limits” lists within five years, the ingredient would be prohibited from use in cosmetic products. *Id.*

although the FDA would apply a presumption of safety to any cosmetic made solely out of ingredients on the “safe without limits list” or out of ingredients in compliance with the “prohibited and restricted list.”<sup>198</sup> The FDA would publish a list of ingredients and cosmetics containing or creating contaminants,<sup>199</sup> and establish testing requirements for cosmetics manufacturers and ingredient suppliers.<sup>200</sup> The SCA of 2011 would also require manufacturers to file a statement with the FDA concerning each cosmetic product produced.<sup>201</sup> Manufacturers, packagers, retailers, and distributors would have to notify the FDA if they had reason to believe that a cosmetic product was adulterated or misbranded in an unsafe manner.<sup>202</sup> The SCA of 2011 would grant the FDA authority to request voluntary recalls, order cessation of distribution, and issue mandatory recall orders.<sup>203</sup> The proposed legislation would also provide for a petition process by which the public could request the FDA to take specific actions on ingredients.<sup>204</sup> In addition, the

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198. H.R. 2359 § 617. The FDA could still require a manufacturer to demonstrate a cosmetic product’s safety if it had reason to believe that the product might not meet the safety standard. *Id.*

199. H.R. 2359 § 618. The list would include “ingredients used in cosmetics that may contain contaminants,” “combinations of ingredients that may create contaminants when such ingredients interact,” “contaminants that may leach from product packaging into a cosmetic,” and “any other contaminant of cosmetics identified by the Secretary.” *Id.*

200. *Id.*

201. H.R. 2359 § 619. The statement would contain “the registration number of the manufacturing establishment where the cosmetic is manufactured or, if the same cosmetic is manufactured in more than 1 establishment, the registration number of each establishment where it is manufactured,” “the registration number of the establishment responsible for distributing the cosmetic,” “the brand name and the product name for the cosmetic,” “the applicable use for the cosmetic,” “the ingredient list as it appears on the cosmetic label or insert, including the particle size range of any nanoscale cosmetic ingredients,” “any warnings and directions for use from the cosmetic label or insert,” and “the title and full contact information for the individual responsible for submitting and maintaining such statement.” *Id.*

202. H.R. 2359 § 620(a).

203. H.R. 2359 § 620(b-f). The FDA could order cessation of distribution if it found reason to believe that “the use of, or exposure to, a cosmetic may cause serious adverse health effects or death to humans,” “the cosmetic is misbranded,” or “the cosmetic is manufactured, packaged, or distributed by an unregistered facility.” H.R. 2359 § 620(c). The recall provisions would provide for an appeals process. H.R. 2359 § 620(c), H.R. 2359 § 620(e). In the event of a recall, the FDA would have the power to order a producer to reveal supply chain information. H.R. 2359 § 620(g).

204. H.R. 2359 § 621. Such actions could include “prohibit[ing] or restrict[ing] an ingredient for use in cosmetics and list[ing] such ingredient on the [prohibited or restricted] list,” “remov[ing] an ingredient from the list of ingredients that are safe without limits,”

legislation would require manufacturers, packagers, and distributors to report any adverse health effects stemming from their cosmetic products, and make such reports publicly accessible.<sup>205</sup> Although limited to cosmetic products, the SCA of 2011 would establish a labeling regime supported by information acquisition provisions and enforcement authority.

The Environmental Protection Agency<sup>206</sup> also exercises substantial authority to regulate the production of chemicals under the Toxic Substances Control Act (TSCA).<sup>207</sup> Unlike the FHSA, many of the TSCA's provisions apply prior to the release of chemical products into the marketplace,<sup>208</sup> including "premanufacture notification" to the EPA of intended production or importation of a

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"add[ing] an ingredient to the priority assessment list," or "add[ing] an ingredient to the list of contaminants." *Id.*

205. H.R. 2359 § 622. A report would include "[t]he identity of the individual experiencing the adverse health effect," "[a]n identifiable report of such effect," "[t]he name of the cosmetic suspected of causing such effect," and "[a] description of the adverse health effect." *Id.*

206. The EPA also operates Design for the Environment ("DfE"), a voluntary certification program that permits chemical products to bear a seal on their labels if they meet certain health, environmental, and performance standards, and pass review by EPA scientists. *Frequent Questions—Design for the Environment (DfE)*, ENVTL. PROT. AGENCY, <http://www.epa.gov/dfe/faqs.html> (last updated Aug. 18, 2011). The EPA has established Standards for Safer Cleaning Products as well as criteria for separate types of such products. *EPA's DfE Standard for Safer Cleaning Products (SSCP)*, ENVTL. PROT. AGENCY (Apr. 2011), available at <http://www.epa.gov/dfe/pubs/projects/gfcp/standard-for-safer-cleaning-products.pdf>; *DfE's Standard and Criteria for Safer Chemical Ingredients—Design for the Environment (DfE)*, ENVTL. PROT. AGENCY, <http://www.epa.gov/dfe/pubs/projects/gfcp/index.htm> (last visited Aug. 18, 2011). The EPA permits the use of the DfE seal on products that contain "only those ingredients that pose the least concern among chemicals in their class." *What Does the DfE Label Mean?—Design for the Environment (DfE)*, ENVTL. PROT. AGENCY, <http://www.epa.gov/dfe/pubs/projects/formulat/label.htm> (last updated Aug. 18, 2011). The DfE program also establishes best practices for industries, identifies safer alternative products, and partners with industries to determine ways to reduce the use of toxins and evaluate health and environmental concerns. *About Us—Design for the Environment (DfE)*, ENVTL. PROT. AGENCY, <http://www.epa.gov/dfe/pubs/about/index.htm> (last updated Aug. 18, 2011). However, the DfE program is entirely voluntary and does not provide for public ingredient disclosure or labeling. *Id.*

207. Toxic Substances Control Act, Pub. L. No. 94-469, 90 Stat. 2003 (1976) (codified as amended at 15 U.S.C. §§ 2601–2692 (2006)). Like the FHSA, the TSCA does not apply to pesticides covered by the FIFRA and food, drugs, and cosmetics covered by the FD&C Act. 15 U.S.C. § 2602(2)(B) (2006). The TSCA also exempts mixtures of chemicals, although the individual chemicals composing the mixtures would likely still be subject to the TSCA. *Id.*

208. RONALD BRICKMAN ET AL., CHEMICAL REGULATION AND CANCER: A CROSS-NATIONAL STUDY OF POLICY AND POLITICS 456 (1982).



new chemical substance.<sup>209</sup> While the TSCA does not provide for any labeling of the substances it regulates, it does mandate extensive data collection by the EPA and reporting by manufacturers.<sup>210</sup> Furthermore, the TSCA confers on the EPA the powers to mandate testing of chemicals believed to pose a risk to health or the environment<sup>211</sup> and to limit their production.<sup>212</sup> However, chemicals produced prior to passage of the TSCA “were assumed safe until proven dangerous and could be used with no limitations.”<sup>213</sup> Before ordering testing or limiting or banning production, the EPA must show that a chemical “may present an unreasonable risk of injury to health or the environment.”<sup>214</sup> Moreover, the TSCA does not mandate

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209. 15 U.S.C. § 2604(a)(1) (2006); *see also* CYNTHIA A. LEWIS & JAMES M. THUNDER, FEDERAL CHEMICAL REGULATION: TSCA, EPCRA AND THE POLLUTION PREVENTION ACT 12 (1997).

210. 15 U.S.C. § 2607(a)-(b) (2006); *see also* LEWIS & THUNDER, *supra* note 209, at 12.

211. 15 U.S.C. § 2603 (2006).

212. 15 U.S.C. § 2605(a)(2)(B) (2006).

213. JOEL TICKNER & YVE TORRIE, PRESUMPTION OF SAFETY: LIMITS OF FEDERAL POLICIES ON TOXIC SUBSTANCES IN CONSUMER PRODUCTS, LOWELL CTR. FOR SUSTAINABLE PROD. 6 (Feb. 2008), *available at* <http://www.chemicalspolicy.org/downloads/UMassLowellConsumerProductBrief.pdf>; Richard Denison, *10 Essential Elements in TSCA Reform*, 39 ENVTL. L. REP. 10,020, 10,020 (2009), *available at* [http://www.edf.org/documents/9279\\_Denison\\_10\\_Elements\\_TSCA\\_Reform.pdf](http://www.edf.org/documents/9279_Denison_10_Elements_TSCA_Reform.pdf).

214. 15 U.S.C. § 2603(a) (2006). The Fifth Circuit’s decision in *Corrosion Proof Fittings v. E.P.A.*, 947 F.2d 1201 (5th Cir. 1991), exemplifies the difficulties faced by the EPA under this standard. Rawlins, *supra* note 17, at 34–35. The court vacated the EPA’s attempt to ban asbestos and held that the EPA failed to adequately evaluate less burdensome alternatives and the “toxicity of likely substitute products that will be used to replace asbestos goods.” *Corrosion Proof Fittings*, 947 F.2d at 1216–20, 1229–30; Rawlins, *supra* note 17, at 34–35. The court also criticized the merits of the EPA’s cost-benefit analyses. *Corrosion Proof Fittings*, 947 F.2d at 1216–20, 1229–30; Rawlins, *supra* note 17, at 34–35. As a result of this decision, the EPA “deemphasized” this method of regulating chemicals, apparently finding it “too resource-intensive and too subject to subsequent court challenges to justify the effort.” ELIZABETH C. BROWN ET AL., TSCA DESKBOOK 58 (1999). Thus, despite having the power to limit the production of chemicals posing an “unreasonable risk,” the EPA has only exercised that power five times since 1976 (over polychlorinated biphenyls (PCBs), chlorofluorocarbons (CFCs), dioxins, asbestos, and hexavalent chromium). U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-05-458, CHEMICAL REGULATION: OPTIONS EXIST TO IMPROVE EPA’S ABILITY TO ASSESS HEALTH RISKS AND MANAGE ITS CHEMICAL REVIEW PROGRAM 58–60 (2005); *see also* Andrew Hanan, Note, *Pushing the Environmental Regulatory Focus a Step Back: Controlling the Introduction of New Chemicals Under the Toxic Substances Control Act*, 18 AM. J.L. & MED. 395 (1992) (reviewing burdens placed on the EPA under *Corrosion Proof Fittings* and arguing that proper regulation of toxic substances requires greater agency deference); Albert C. Lin, *Size Matters: Regulating Nanotechnology*, 31 HARV. ENVTL. L. REV. 349, 367 (2007) (arguing that “the evidentiary burdens and procedural requirements that TSCA imposes on [the] EPA” make it unsuitable for regulating products of nanotechnology).

testing or data submission concerning toxicity with the premanufacture notification.<sup>215</sup> Pursuant to the TSCA,<sup>216</sup> the EPA maintains the TSCA Inventory, a list of chemicals currently produced in or imported into the United States.<sup>217</sup> The EPA also requires the filing of a variety of reports concerning a manufacturer's chemical products.<sup>218</sup> However, the TSCA restricts public access to this information, protecting the confidentiality of much of the data except health and safety studies<sup>219</sup> and some voluntarily submitted

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215. Richard Denison, *EPA's New Chemicals Program: TSCA Dealt EPA a Very Poor Hand*, ENVTL. DEF. FUND, (Apr. 16, 2009), available at <http://blogs.edf.org/nanotechnology/2009/04/16/epas-new-chemicals-program-tsca-dealt-epa-a-very-poor-hand/>; Wilson & Schwarzman, *supra* note 19, at 1205. While the EPA has authority under the Act to require testing of chemicals, this may only occur after the EPA issues a testing rule. U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 214, at 19. This requires some basis for concluding the chemical poses a risk and creates an expensive and time-consuming hurdle for the EPA. Rawlins, *supra* note 17, at 32–33. The result is “what amounts to a classic Catch-22, government must already have information sufficient to document potential risk, or at the very least, extensive exposure, in order to require the development of information sufficient to determine whether there is actual risk.” Denison, *supra* note 213, at 10,020. As a result, the EPA has required testing of only about 200 of the 62,000 chemicals in production at the enactment of the Act in 1976. *Id.*; OVERVIEW: OFFICE OF POLLUTION PREVENTION AND TOXICS PROGRAMS, ENVTL. PROT. AGENCY 15 (2007), available at <http://www.epa.gov/oppt/pubs/oppt101c2.pdf>.

216. 15 U.S.C. § 2607(b) (2006).

217. LEWIS & THUNDER, *supra* note 209, at 35. For purposes of the TSCA, a “new” chemical is one not already included in the Inventory. *Id.*

218. 15 U.S.C. § 2608(a) (2006); 15 U.S.C. § 2607(c)-(e) (2006). The EPA has mandated a broad spectrum of reporting requirements under the Act, including reports concerning quantities and production facilities of chemicals subject to the Preliminary Assessment Information Rule, updating of data in the TSCA Inventory, reporting of data concerning health and safety, and reporting of allegations of negative impacts on health and the environment. 40 C.F.R. § 712.28 (2009); 40 C.F.R. §§ 710.23–710.32 (2009); 40 C.F.R. §§ 716.1–716.65 (2009); 40 C.F.R. §§ 717.1–717.19 (2009); *see also* LEWIS & THUNDER, *supra* note 209, at 107–40. The EPA also monitors the reporting of chemicals that could pose “a substantial risk of injury to health or the environment,” as required under Section 8(e) of the TSCA. 15 U.S.C. § 2607(e) (2006); OFFICE OF PESTICIDES AND TOXIC SUBSTANCES, ENVTL. PROT. AGENCY, TSCA SECTION 8(E) REPORTING GUIDE 1 (1991), available at <http://www.epa.gov/oppt/tsca8e/pubs/1991guidance.pdf>. Though the EPA considers such reporting “critically important,” it has not issued reporting regulations because it has determined Section 8(e) is “self-implementing.” OFFICE OF PESTICIDES AND TOXIC SUBSTANCES, *supra*.

219. 15 U.S.C. § 2613 (2006); *see also* U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 214, at 31–34. In 2010, the EPA for the first time provided public access to the non-confidential TSCA inventory. *TSCA Chemical Substance Inventory*, ENVTL. PROT. AGENCY, <http://www.epa.gov/oppt/existingchemicals/pubs/tscainventory/index.html> (last updated Mar. 15, 2011). Currently, the Inventory contains “over 83,000 chemical substances.” *TSCA Inventory*, DATA.GOV, <http://www.data.gov/raw/1630> (last updated Feb. 20, 2011).

information.<sup>220</sup> The TSCA also requires the EPA to file a report with an agency administering another law regulating chemicals when the EPA determines that use of that law could reduce an “unreasonable risk of injury to health or the environment.”<sup>221</sup> Theoretically, the TSCA grants the EPA broad authority to regulate chemical manufacturing.<sup>222</sup> In practice, however, administrative constraints, including the high standard of evidence required before the EPA can take action, have substantially narrowed its reach.<sup>223</sup>

In the 112th Congress, Representatives Bobby Rush and Henry Waxman introduced the Toxic Chemicals Safety Act of 2010 (TCSA) in the House of Representatives, and Senator Frank Lautenberg introduced the Safe Chemicals Act of 2010 (SCA of 2010) in the Senate.<sup>224</sup> Both pieces of legislation sought to reform the TSCA.<sup>225</sup> Among other provisions, the TCSA and the SCA of 2010 would require manufacturers to submit “data sets” to the EPA so that the EPA could make safety determinations.<sup>226</sup> The proposed legislation

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220. LEWIS & THUNDER, *supra* note 209, at 205–06.

221. 15 U.S.C. § 2608(a) (2006).

222. Rawlins, *supra* note 17, at 32–33.

223. *Id.* To address some of these administrative constraints, EPA Administrator Lisa P. Jackson announced new efforts in 2009 “to enhance the Agency’s current chemicals management program within the limits of existing authorities,” including “New Regulatory Risk Management Actions,” “Development of Chemical Action Plans,” “Requiring Information Needed to Understand Chemical Risks,” “Increasing Public Access to Information About Chemicals,” and “Engaging Stakeholders in Prioritizing Chemicals for Future Risk Management Action.” ENVTL. PROT. AGENCY, ENHANCING EPA’S CHEMICAL MANAGEMENT PROGRAM (2009), available at <http://www.epa.gov/oppt/existingchemicals/pubs/Existing.Chem.Fact.sheet.pdf>. This effort remains ongoing, but in 2009 Administrator Jackson also announced the EPA’s support for TSCA reform. Lisa P. Jackson, Administrator, Env’tl. Protection Agency, Remarks to the Commonwealth Club of San Francisco, As Prepared (Sept. 29, 2009), available at <http://yosemite.epa.gov/opa/admpress.nsf/8d49f7ad4bbcf4ef852573590040b7f6/fc4e2a8c05343b3285257640007081c5!OpenDocument>.

224. Toxic Chemicals Safety Act of 2010, H.R. 5820, 112th Cong. (2010); Safe Chemicals Act of 2010, S. 3209, 112th Cong. (2010); Press Release, Office of Congressman Bobby Rush, Chairmen Rush, Waxman Release H.R. 5820, The Toxic Chemicals Safety Act (July 22, 2010), available at [http://www.house.gov/list/press/il01\\_rush/pr\\_100722\\_hr5820.shtml](http://www.house.gov/list/press/il01_rush/pr_100722_hr5820.shtml); Press Release, Office of Sen. Frank R. Lautenberg, Lautenberg Introduces “Safe Chemicals Act” to Protect Americans from Toxic Chemicals (Apr. 15, 2010), available at <http://lautenberg.senate.gov/newsroom/record.cfm?id=323863>.

225. Press Release, Office of Congressman Bobby Rush, *supra* note 224; Press Release, Office of Sen. Frank R. Lautenberg, *supra* note 224.

226. H.R. 5820 § 4(a); S. 3209 § 5(a). The minimum data set under the TCSA would have to provide information including the “(i) chemical identity; (ii) substance characteristics; (iii) biological and environmental fate and transport; (iv) toxicological properties; (v) volume

also would permit the EPA to, by order, “require testing in addition to the requirements for the minimum data set.”<sup>227</sup> Additionally, both Acts would require manufacturers to submit notice to the EPA when manufacturing a new chemical, or when employing a previously produced chemical for a new use, and would not permit the manufacture or use of the chemical unless the EPA first found that the chemical met certain safety standards and conditions.<sup>228</sup> Both Acts would require the EPA to establish a “priority list” of at least 300 chemicals currently in use, and apply a safety standard to those chemicals.<sup>229</sup> The manufacturer would “bear the burden of proving that the chemical substance” met the safety standard.<sup>230</sup> The EPA would make safety determinations publicly available, and would

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manufactured, processed, or imported; (vi) intended uses; and (vii) exposures from all stages of the chemical substance or mixture’s lifecycle that are known or reasonably foreseeable to the party submitting the data set.” H.R. 5820 § 4(a). The SCA of 2010 would leave the definition of the data set to the EPA, and would require only “information on substance characteristics and on hazard, exposure, and use of chemical substances and mixtures that the Administrator anticipates will be useful in conducting safety standard determinations.” S. 3209 § 5(a).

227. H.R. 5820 § 4(b); S. 3209, § 5(b) (adopting similar language).

228. H.R. 5820 § 5(a); S. 3209 § 5(a). The TCSA would permit the EPA to exempt the use of a chemical if the EPA determined a use was a “critical use,” defined as one “in the paramount interest of national security;” or one whose “restriction would significantly disrupt the national economy;” or one that “is a critical or essential use,” and “no feasible safer alternative for the specified use is available,” or “the specified use of the chemical substance or mixture provides a net benefit to health or the environment when compared to all available alternatives.” H.R. 5820 § 5(a); H.R. 5820 § 6(e). The SCA of 2010 provides a method by which chemicals not anticipated to be “manufactured in a volume of more than 1,000,000 pounds annually or released into the environment in a volume of more than 100,000 pounds annually” could be permitted to be manufactured without meeting the safety standards, if it also was not, and was not anticipated to be, a “known, probable, or suspected reproductive, developmental, neurological, or immunological toxicant, carcinogen, mutagen, or endocrine disruptor, or has other toxicological properties of concern;” “persistent and bioaccumulative;” “found in human cord blood, or otherwise found in human blood, fluids, or tissue, unless the chemical substance or metabolite or degradation product is naturally present at the level commonly found in that medium;” or “found in food, drinking water, ambient or indoor air, residential soil, or house dust, unless the chemical substance or metabolite or degradation product is naturally present at the level commonly found in that medium.” S.3209 § 5(a).

229. H.R. 5820 § 6. The TCSA’s safety standard would require that “with regard to public health, there is a reasonable certainty that no harm will result, including to vulnerable populations; and . . . the public welfare is protected.” *Id.* The SCA of 2010 would similarly apply a “reasonable certainty of no harm” standard, requiring that aggregate and cumulative “exposure of the general population or of any vulnerable population to the chemical substance or mixture presents a negligible risk of any adverse effect on the general population or a vulnerable population.” S.3209 § 4(23).

230. H.R. 5820 § 6; S. 3209 § 7.

restrict the manufacture of chemicals that did not meet the safety standards (although the TCSA would permit exemptions for “critical uses”).<sup>231</sup> Under the proposed legislation, a manufacturer would have to submit a declaration for each chemical and mixture that would include a variety of safety data known to the manufacturer.<sup>232</sup> The EPA would use this information to establish a publicly accessible internet database concerning chemical substances and mixtures and their toxicity.<sup>233</sup> The TCSA and the SCA of 2010 would thus impose more extensive testing, safety, and disclosure requirements than federal law currently mandates, although they would not establish an affirmative labeling requirement of the kind anticipated by the Household Product Labeling Act.<sup>234</sup> In 2011, Senator Lautenberg introduced the Safe Chemicals Act of 2011, legislation substantially similar to the SCA of 2010.<sup>235</sup>

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231. H.R. 5820 § 6; S. 3209 § 7.

232. H.R. 5820 § 8(a); S. 3209 § 9. Under the TCSA, the information would have to reveal the following: the “chemical identity of the chemical substance or mixture,” the “name and location of each facility” manufacturing it, the “number of individuals exposed, and reasonable estimates of the number who will be exposed, to such substance or mixture in their places of employment and the duration of such exposure,” and a list of “health and safety studies conducted or initiated by or for, known to, or reasonably ascertainable by the manufacturer or processor.” H.R. 5820 § 8(a). In addition, manufacturers would have to supply information known to or readily ascertainable by the manufacturer regarding the “physical, chemical, and toxicological properties of the chemical substance or mixture,” “the categories or proposed categories of intended use,” amounts manufactured and reasonable estimates of amounts to be manufactured, byproducts of manufacturing, “exposure information,” “conditions currently placed on the chemical substance or mixture due to regulation” or voluntary action, and “any information indicating that a mixture including the chemical substance has substance characteristics that are different from the substance characteristics of the named chemical substances.” *Id.* The SCA of 2010 would require the disclosure of similar information. S. 3209 § 9.

233. *Id.* § 8(d).

234. For a summary of the TCSA, see COMMITTEE ON ENERGY AND COMMERCE, HOUSE OF REPRESENTATIVES, SECTION-BY-SECTION ON DISCUSSION DRAFT OF THE “TOXIC CHEMICALS SAFETY ACT OF 2010” (2010), available at [http://democrats.energycommerce.house.gov/Press\\_111/20100415/TCSA.Section.by.Section.04.15.2010.pdf](http://democrats.energycommerce.house.gov/Press_111/20100415/TCSA.Section.by.Section.04.15.2010.pdf).

235. Safe Chemicals Act of 2011, S. 847, 112th Cong. (2011); Press Release, Office of Sen. Frank R. Lautenberg, Sen. Lautenberg Introduces “Safe Chemicals Act of 2011” (Apr. 14, 2011), available at <http://lautenberg.senate.gov/newsroom/record.cfm?id=332785>. For a summary of the significant differences between the SCA of 2010 and the Safe Chemicals Act of 2011, see RICHARD A. DENISON, ENVTL. DEF. FUND, SUMMARY OF CHANGES IN SAFE CHEMICALS ACT OF 2011 VS. 2010 (May 9, 2011), available at <http://www.saferchemicals.org/PDF/Summary-of-key-changes-in-Safe-Chemicals-Act-of-2011-vs-2010-revised.pdf>.

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the EPA also has primary authority to regulate the labeling of pesticides, fungicides, and rodenticides.<sup>236</sup> The FIFRA considers a pesticide<sup>237</sup> misbranded if it does not bear a label containing an “ingredient statement”; the manufacturer’s registration number; directions for proper use of the product; any necessary “warning or caution” statements; the “use classification” for which the product was registered; the name and address of the manufacturer; the “name, brand, or trademark” of the product; and “the net weight or measure of the content.”<sup>238</sup> If the pesticide contains “highly toxic” ingredients, the label must also display “the skull and crossbones”; “the word ‘poison’ prominently in red on a background of distinctly contrasting color”; and “a statement of a practical treatment (first aid or otherwise) in case of poisoning.”<sup>239</sup> The “ingredient statement” must contain “the name and percentage of each active ingredient and the total percentage of all inert ingredients.”<sup>240</sup> Thus, under the FIFRA, the EPA has established another labeling regulatory scheme separate from those employed by other agencies, with somewhat stricter requirements reflecting the known toxicity of the contents.<sup>241</sup>

Some members of Congress have recognized deficiencies in current household chemical labeling practices and have introduced

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236. Federal Insecticide, Fungicide, and Rodenticide Act, Pub. L. No. 80-104, 61 Stat. 163 (1947) (codified as amended at 7 U.S.C. § 136-136(y)). Congress transferred authority under the FIFRA from the USDA to the EPA in 1972. Reorg. Plan No. 3 of 1970, 35 Fed. Reg. 15,623 (Oct. 6, 1970); see also Michael T. Olexa, *Pesticide Use and Impact: FIFRA and Related Regulatory Issues*, 68 N.D. L. REV. 445, 445 (1992).

237. The FIFRA defines a pesticide as “(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer.” 7 U.S.C. § 136(u) (2006).

238. 7 U.S.C. § 136(q). The labeling also must not mislead consumers, and all information required to appear in the labeling must be featured prominently enough so as to render it “likely to be read and understood by the ordinary individual under customary conditions of purchase and use.” *Id.*

239. *Id.*

240. 7 U.S.C. § 136(n) (2006). The ingredient statement must be “presented or displayed under customary conditions of purchase.” 7 U.S.C. § 136(q) (2006).

241. The EPA labeling regulations are also distinguished by their relative focus on environmental impacts of the regulated products as well as their effects on consumer health. See, e.g., 7 U.S.C. § 136(q)(1)(F) (2006) (requiring that directions for use be “adequate to protect health and the environment”); 7 U.S.C. § 136(q)(1)(G) (2006) (requiring that “warning or caution” statements be “adequate to protect health and the environment”).

legislation to address them. In 2008, Senator Frank Lautenberg of New Jersey introduced the Kid-Safe Chemicals Act (KSCA) in the Senate,<sup>242</sup> and Representative Hilda Solis of California—now Secretary of Labor under President Barack Obama<sup>243</sup>—introduced it in the House of Representatives.<sup>244</sup> Among other provisions, the KSCA would amend the TSCA to require chemical manufacturers to test the safety of their products and certify that they meet the safety standard established in the bill, as well as submit updated information to the EPA if new data concerning a product's toxicity appears.<sup>245</sup> Manufacturers would not be allowed to sell new chemical products prior to a safety determination by the EPA.<sup>246</sup> The bill would also impose on the EPA the duty to regularly assess the safety of chemicals sold in commerce, beginning with a list of “priority” chemicals.<sup>247</sup> The bill would require the EPA to conduct “biomonitoring” to determine the amount of commonly sold chemicals in human tissue, as well as any other chemicals about which the EPA has particular concerns.<sup>248</sup> Perhaps most importantly

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242. Kid-Safe Chemicals Act, S. 3040, 110th Cong. (2008).

243. *Meet Secretary of Labor Hilda L. Solis*, U.S. DEP'T. OF LABOR, <http://www.dol.gov/sec/welcome.htm> (last visited Sept. 20, 2011).

244. Kid-Safe Chemicals Act, H.R. 6100, 110th Cong. (2008). The bills failed to pass in the 110th Congress, but Senator Lautenberg indicated his intent to reintroduce similar legislation in the future. *S. 3040 [110th]: Kid-Safe Chemicals Act of 2008*, GOVTRACK.US, <http://www.govtrack.us/congress/bill.xpd?bill=s110-3040> (last visited Sept. 20, 2011); *H.R. 6100 [110th]: Kid-Safe Chemicals Act of 2008*, GOVTRACK.US, <http://www.govtrack.us/congress/bill.xpd?bill=h110-6100> (last visited Sept. 20, 2011); *Oversight Hearing on the Federal Toxic Substances Control Act: Hearing Before the Full Committee and Subcommittee on Superfund, Toxics and Environmental Health*, 111th Cong. (2009) (Statement of Sen. Frank R. Lautenberg), available at [http://www.epw.senate.gov/public/index.cfm?FuseAction=Hearings.Statement&Statement\\_ID=117d5500-2696-453a-a8a2-3a56f2a63d6b](http://www.epw.senate.gov/public/index.cfm?FuseAction=Hearings.Statement&Statement_ID=117d5500-2696-453a-a8a2-3a56f2a63d6b). In 2010, Senator Lautenberg introduced the Safe Chemicals Act of 2010. See *supra* notes 224–34 and associated text.

245. H.R. 6100 § 502; S. 3040 § 502; see also *Kid-safe Chemicals Are Now Within Our Reach*, ENVTL. WORKING GRP., <http://www.ewg.org/kid-safe-chemicals-act-blog/kid-safe-chemicals-act> (last visited Sept. 20, 2011). The bill mandates a “safety standard” that would provide “a reasonable certainty that no harm will be caused by aggregate exposure of a fetus, infant, child, worker, or member of other sensitive subgroup to the chemical substance” and would be “requisite to protect the public welfare from any known or anticipated adverse effects associated with the chemical substance.” H.R. 6100 § 501(5); S. 3040 § 501(5).

246. H.R. 6100 § 504(b)(3); S. 3040 § 504(b)(3).

247. H.R. 6100 § 504(b)(1); S. 3040 § 504(b)(1). The bills would require reassessments every fifteen years. H.R. 6100 § 504(b)(2); S. 3040 § 504(b)(2).

248. H.R. 6100 § 506; S. 3040 § 506.

for the informational role served by labeling, the bill would mandate that the EPA create a publicly accessible database of “any information provided to the Administrator relating to the properties and hazards of a chemical substance” and “any other nonconfidential information relating to a chemical substance.”<sup>249</sup> The bill would expand the EPA’s authority under the TSCA to protect vulnerable groups from chemical hazards and to inform the public about those hazards.<sup>250</sup>

In the 111th Congress, Senator Al Franken<sup>251</sup> introduced legislation directly addressing the need for improved household chemical labeling in the Senate,<sup>252</sup> and Representative Steve Israel<sup>253</sup> introduced such legislation in the House of Representatives.<sup>254</sup> The bill, known as the Household Product Labeling Act (HPLA), would have mandated that all “household cleaning product[s] or similar product[s]”<sup>255</sup> carry labels displaying “a complete and accurate list of all the product’s ingredients.”<sup>256</sup> The HPLA would have treated any product not bearing such a label as “a misbranded hazardous substance” as defined by the FHSA.<sup>257</sup> The HPLA would have granted the CPSC authority to enforce the new legislation through regulation.<sup>258</sup> The legislation represented an opportunity to structure an appropriate household chemical labeling regime, and indicated that legislators and the public have recognized the need for such

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249. H.R. 6100, § 512; S. 3040 § 512.

250. The legislation puts a particular focus on vulnerable groups such as “fetus[es], infant[s], child[ren], worker[s],” and other groups. H.R. 6100 § 501(5); S. 3040 § 501(5). It also addresses concerns with “prenatal exposure” in special sections of the proposed laws. H.R. 6100 § 505; S. 3040 § 505.

251. *Household Cleaning Product Labeling*, AL FRANKEN—SENATOR FOR MINNESOTA, <http://www.franken.senate.gov/?p=issue&id=262> (last visited Sept. 20, 2011).

252. Household Product Labeling Act of 2009, S. 1697, 111th Cong.

253. Consumer Protection, STEVE ISRAEL—REPRESENTING THE 2ND DISTRICT OF NEW YORK, [http://israel.house.gov/index.php?option=com\\_content&view=article&id=611&Itemid=89](http://israel.house.gov/index.php?option=com_content&view=article&id=611&Itemid=89) (last visited Sept. 20, 2011).

254. Household Product Labeling Act of 2009, H.R. 3057, 111th Cong.

255. The bill would have defined a “household cleaning product or similar product” as any substance that is “customarily produced and distributed for use in or about a household as a cleaning agent, pesticide, epoxy, paint or stain, or similar substance.” H.R. 3057 § 2(b); S. 1697 § 2(b).

256. H.R. 3057 § 2(a); S. 1697 § 2(a).

257. H.R. 3057 § 2(a); S. 1697 § 2(a).

258. H.R. 3057 § 2(c); S. 1697 § 2(c).



labeling.<sup>259</sup> However, the bills reached the Senate Committee on Commerce, Science, and Transportation and the House Subcommittee on Commerce, Trade, and Consumer Protection, but were not voted on in the 111th Congress.<sup>260</sup> While other legislation that would serve some of the same purposes as the HPLA, such as the TSCA, the SCA of 2010, and the SCA of 2011, have been introduced since the HPLA, the HPLA itself has not as yet been reintroduced.

While federal law provides the majority of chemical labeling requirements, numerous state laws also mandate various labeling and information disclosures.<sup>261</sup> California's Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986,<sup>262</sup> is one of the most important state laws impacting labeling.<sup>263</sup> Proposition 65 bars any "person in the course of doing business" in the state from "knowingly and intentionally expos[ing] any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual."<sup>264</sup> Any

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259. Madeleine Baran, *Sen. Franken Introduces Bill for Labeling Household Products*, MINNESOTA PUB. RADIO (Sept. 23, 2009), available at <http://minnesota.publicradio.org/display/web/2009/09/23/franken-cleaning-legislation/>.

260. S. 1697 [111th]: *Household Product Labeling Act of 2009*, GOVTRACK.US, <http://www.govtrack.us/congress/bill.xpd?bill=s111-1697> (last visited Sept. 20, 2011); H.R. 3057 [111th]: *Household Product Labeling Act of 2009*, GOVTRACK.US, <http://www.govtrack.us/congress/bill.xpd?bill=h111-3057> (last visited Sept. 20, 2011).

261. Christine Y. LeBel, *Household Toxics: The Choice Is (or Should Be) Yours*, 21 NAT. RESOURCES & ENVT. 71, 71 (2007).

262. Safe Drinking Water and Toxic Enforcement Act of 1986, CAL. HEALTH & SAFETY CODE §§ 25249.5–25249.25 (West 2010). Since its enactment in 1985, numerous defendants and commentators have argued that various federal laws preempt Proposition 65, but the law still remains in effect. *See, e.g.*, *People ex rel. Lungren v. Cotter & Co.*, 53 Cal. App. 4th 1, 373 (1997) (ruling the FHSA does not preempt Proposition 65); *Chemical Specialties Mfrs. Ass'n, Inc. v. Allenby*, 958 F.2d 941 (9th Cir. 1992) (ruling that neither the FIFRA nor the FHSA preempt Proposition 65); Harry J. Katrichis & Roger A. Keller, Jr., *Putting California's Labeling Horse Back Into the Federal Labeling Barn*, 7 HASTINGS W.-N.W. J. ENVT. L. & POL'Y 19 (2000) (arguing that the FHSA preempts Proposition 65).

263. Tim T. Phipps et al., *The Political Economics of California's Proposition 65*, 71 AM. J. AGRIC. ECON. 1286, 1286 (1989).

264. CAL. HEALTH & SAFETY CODE § 25249.6. A warning can "be provided by general methods such as labels on consumer products, inclusion of notices in mailings to water customers, posting of notices, placing notices in public news media, and the like, provided that the warning accomplished is clear and reasonable." *Id.* § 25249.11(f). The actual warning provided can vary somewhat depending on the product involved and the risk presented; a typical warning would read either "WARNING: This product contains a chemical known to the State of California to cause cancer" or "WARNING: This product contains a chemical known

violator “may be enjoined in any court of competent jurisdiction” and “shall be liable for a civil penalty not to exceed two thousand five hundred dollars (\$2,500) per day for each violation.”<sup>265</sup> The law also requires the Governor of California to publish “a list of those chemicals known to the state to cause cancer or reproductive toxicity.”<sup>266</sup> The law relies on court actions commenced by either the state attorney general or private parties to achieve its goals,<sup>267</sup> placing an emphasis on citizen action rather than on agency enforcement.<sup>268</sup> The results are controversial. Critics have noted the high cost to

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to the State of California to cause birth defects or other reproductive harm.” CAL. CODE REGS. tit. 27, § 25603.2 (2008).

265. CAL. HEALTH & SAFETY CODE § 25249.7.

266. *Id.* § 25249.8. Under Proposition 65:

A chemical is known to the state to cause cancer or reproductive toxicity within the meaning of this chapter if in the opinion of the state’s qualified experts it has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity, or if a body considered to be authoritative by such experts has formally identified it as causing cancer or reproductive toxicity, or if an agency of the state or federal government has formally required it to be labeled or identified as causing cancer or reproductive toxicity.

*Id.* § 25249.8(b). A chemical poses “no significant risk,” and therefore does not require a warning statement, only if it would “result in one excess case of cancer [or less] in an exposed population of 100,000, assuming lifetime exposure at the level in question . . . except where sound considerations of public health support an alternative level . . .,” CAL. CODE REGS. tit. 27, § 25703(b) (2008), or would cause “no observable [reproductive] effect at one thousand (1,000) times the level in question.” CAL. CODE REGS. tit. 27, § 25801(a) (2008). These amounts “can be orders of magnitude below federal regulatory levels and, of course, below levels set by any other state.” Trenton H. Norris, *Consumer Litigation and FDA-Regulated Products: The Unique State of California*, 61 FOOD & DRUG L.J. 547, 549 (2006). The law places the burden of proof on the manufacturer of a chemical product to show that the product meets the statutory limits. CAL. HEALTH AND SAFETY CODE § 25249.10(c).

267. CAL. HEALTH & SAFETY CODE 25249.7. These provisions, along with a provision granting 25% of penalties to the plaintiff, *id.* § 25192(a)(2), and a California civil procedure provision awarding attorney’s fees for lawsuits conferring “a significant benefit . . . on the general public,” led to a surge in litigation following the passage of Proposition 65. CAL. CIV. PROC. CODE § 1021.5 (West 2008); *see also* Norris, *supra* note 266, at 550–52. However, amendments to this section penalizing frivolous lawsuits, requiring court approval for Proposition 65 settlements, and mandating reporting of those settlements have diminished the impact of the legislation. CAL. HEALTH & SAFETY CODE § 25249.7; *see also* Norris, *supra* note 266, at 550–52.

268. Michael W. Graf, *Regulating Pesticide Pollution in California Under the 1986 Safe Drinking Water and Toxic Exposure Act (Proposition 65)*, 28 ECOLOGY L.Q. 663, 718–19 (2001).

businesses of defending against Proposition 65 lawsuits,<sup>269</sup> the potential dilution of federal regulatory power,<sup>270</sup> and the failure to adequately inform consumers beyond a basic warning statement.<sup>271</sup> Defenders praise its success in forcing manufacturers to reformulate their products,<sup>272</sup> the potential for citizen involvement and consequential bypass of sometimes weak and politically hamstrung enforcement agencies,<sup>273</sup> and the placement of the burden of proof and responsibility on manufacturers.<sup>274</sup> Nevertheless, Proposition 65 serves as another possible environmental enforcement model and indicates the potential for state action in the field under the current regulatory structure.<sup>275</sup>

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269. Rick R. Rothman et al., *California's Proposition 65 and the Boy Who Cried Wolf*, 14 NAT. RESOURCES & ENV'T 227, 227 (2000).

270. Norris, *supra* note 266, at 558–60.

271. Clifford Rechtschaffen, *The Warning Game: Evaluating Warnings Under California's Proposition 65*, 23 ECOLOGY L.Q. 303, 332–41 (1996). Critics have also pointed to the problem of “over-warning,” suggesting that businesses will apply labels even when little danger exists and consequently, consumers will begin to ignore labels when they appear on too many products. *Id.* at 355–59.

272. *Id.* at 341–48.

273. Graf, *supra* note 268, at 718–20.

274. Carl Cranor, *Information Generation and Use Under Proposition 65: Model Provisions for Other Postmarket Laws?*, 83 IND. L.J. 609, 621–23 (2008).

275. Indeed, fear of becoming subject to a patchwork of state regulation could encourage industry support of federal labeling legislation, as it did in the case of the Pure Food and Drug Act. Barkan, *supra* note 35; see also Glenn Hess, *Loosening Gridlock: Chemical Industry Hopes Congressional Election Will Spur More Bipartisan Collaboration*, 88 CHEM. & ENG'G NEWS 38, 39 (Oct. 25, 2010) (quoting Peter A. Molinaro, vice president of federal and state government affairs at Dow Chemical, as stating that a “patchwork of 50 different state chemical management laws is not necessarily good for the global competitiveness of this industry”). A few chemical manufacturers have already indicated at least some willingness to disclose the ingredients in their products. For example, SC Johnson, a major global manufacturer of household chemical products, created a website that purports to list all the ingredients in its products. WHAT'S INSIDE SC JOHNSON, <http://www.whatsinsidescjohnson.com> (last visited Sept. 20, 2011). The Clorox Company, Reckitt Benckiser Group, and The Procter & Gamble Company also identify at least some of their ingredients on their websites. *Ingredients Inside*, THE CLOROX CO., <http://www.cloroxcsr.com/ingredients-inside/> (last visited Sept. 20, 2011); *Product Information*, RECKITT BENCKISER GROUP, <http://www.rbnainfo.com/productpro/ProductSearch.do> (last visited Sept. 20, 2011); Procter & Gamble, *Product Safety*, P&G PRODUCT SAFETY, <http://www.pgproductsafety.com/productsafety/index.shtml> (last visited Sept. 20, 2011); see also *Disclosure Watch*, WOMEN'S VOICES FOR THE EARTH, <http://www.womensvoices.org/our-work/safe-cleaning-products/change-corporate-practices/disclosure-watch/> (last visited Sept. 20, 2011).

Although many household chemical manufacturers oppose the HPLA, a group of major manufacturers have also agreed to voluntarily disclose many (but not all) ingredients in their household cleaning products. AMERICAN CLEANING INSTITUTE, CONSUMER PRODUCT

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INGREDIENT COMMUNICATION INITIATIVE (Mar. 2011), available at <http://www.cleaninginstitute.org/assets/1/Page/Ingredient%20Communication%20Model%20fnl%20rev%200311.pdf> [hereinafter AMERICAN CLEANING INSTITUTE, CPICI]; see also Leslie Wayne, *A Fight Grows Over Labeling on Cleaning Products*, N.Y. TIMES, Sept. 19, 2009, at B1, available at <http://www.nytimes.com/2009/09/17/business/energy-environment/17green.html>; Gervin, *supra* note 177, at 334. Recently, chemical industry groups have attempted to use this program as a defense against mandatory disclosure laws, arguing that those laws are unnecessary in light of the voluntary program. See, e.g., Letter from Dennis Griesing, Vice President, Government Affairs & Michelle Radecki, Vice President & General Counsel, Am. Cleaning Inst. to Elizabeth E. Maer, Special Assistant, Commissioner's Policy Office, N.Y. State Dep't of Env'tl. Conservation (Mar. 1, 2011), available at [http://media40.wnyc.net/media/resources/2011/Mar/03/ACL\\_Final\\_Commnets\\_on\\_DEC\\_Proposal\\_fnl\\_dft\\_030111.pdf](http://media40.wnyc.net/media/resources/2011/Mar/03/ACL_Final_Commnets_on_DEC_Proposal_fnl_dft_030111.pdf) (commenting on proposed amendments to New York state disclosure requirements). However, the CPICI only covers intentionally added ingredients, not impurities. AMERICAN CLEANING INSTITUTE, CPICI, *supra*; see also WOMEN'S VOICES FOR THE EARTH, CONSUMERS TO GET MORE INFORMATION ABOUT THE CHEMICALS USED IN CLEANING PRODUCTS—ADDITIONAL INFORMATION STILL NEEDED (2010), available at <http://www.womensvoices.org/wp-content/uploads/2010/08/Industry-Voluntary-Initiative1.pdf> [hereinafter WOMEN'S VOICES FOR THE EARTH, CONSUMERS TO GET MORE INFORMATION]. In practice, even manufacturers that are participating in the program have limited disclosure to only certain categories of ingredients. *Disclosure Watch*, WOMEN'S VOICES FOR THE EARTH, *supra*. The CPICI also does not specify any uniform means of information disclosure, much less a labeling requirement, and does not mandate a particular or consistent nomenclature for ingredients. AMERICAN CLEANING INSTITUTE, CPICI, *supra*; WOMEN'S VOICES FOR THE EARTH, CONSUMERS TO GET MORE INFORMATION, *supra*. More fundamentally, of course, the program relies entirely on industry good will for its enforcement, a policing mechanism with obvious flaws. WOMEN'S VOICES FOR THE EARTH, CONSUMERS TO GET MORE INFORMATION, *supra*. As a result, the program cannot be regarded as an adequate answer to consumers' information needs.

While a willingness to divulge information on a company's own terms does not necessarily equate to a willingness to submit to regulation to release that information, Seventh Generation, a manufacturer of environmentally conscious household products, has sponsored the "Million Baby Crawl," a campaign calling for reform of toxic chemicals law, including ingredient disclosure and testing requirements. Seventh Generation, *Join the Million Baby Crawl*, 7GEN BLOG (Oct. 7, 2009), available at <http://www.seventhgeneration.com/learn/blog/dr-alan-greene-explains-historic-toxic-chemical-reform>. Method Products, a manufacturer of non-toxic, environmentally conscious household cleaning products, produced a commercial in favor of the Household Product Labeling Act, although after complaints regarding certain content in the advertisement which was perceived to conjure images of sexual assault, the commercial was removed. *Shiny Suds Banned by People Against Dirty*, THE INSPIRATION ROOM (Dec. 8, 2009), available at <http://theinspirationroom.com/daily/2009/shiny-suds-banned-by-people-against-dirty/>. Method Products has retained other aspects of its campaign for greater disclosure, however. See *People Against Dirty*, METHOD PRODUCTS, <http://www.methodhome.com/peopleagainstdirty> (last visited Sept. 20, 2011). Both Seventh Generation and Method Products already reveal at least some of the ingredients in their products on their websites. *All Ingredients*, SEVENTH GENERATION, <http://www.seventhgeneration.com/ingredients> (last visited Sept. 20, 2011); *Behind the Bottle*, METHOD PRODUCTS, <http://methodhome.com/behind-the-bottle/natural> (last visited Sept. 20, 2011). While hardly representing the views of a majority of the chemical industry, these efforts indicate that opposition to labeling legislation might not be universal.

Since the passage of Proposition 65, California has continued to pursue initiatives requiring chemical product manufacturers to disclose more information about the ingredients in their products. The Safe Cosmetics Act of 2005<sup>276</sup> requires manufacturers of cosmetic products regulated by the FDA that “contain any ingredient that is a chemical identified as causing cancer or reproductive toxicity” to submit to the state Division of Environmental and Occupational Disease Control a list of those cosmetic products.<sup>277</sup> The statute also permits the Division to conduct investigations of cosmetic products, and to request from the manufacturer any “relevant health effects data and studies.”<sup>278</sup> The California Division of Occupational Safety and Health can then use the results to formulate occupational health standards.<sup>279</sup> In 2008, the California Assembly passed Assembly Bill 1879,<sup>280</sup> and the California Senate passed Senate Bill 509,<sup>281</sup> establishing the Green Chemistry Initiative.<sup>282</sup> Among other provisions, this initiative requires the California Department of Toxic Substances Control (DTSC) to adopt regulations that “establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being a chemical of concern,”<sup>283</sup> and to evaluate “adverse impact[s] on public health or the environment, including air, water, or soil, that may result from the production, use, or disposal” of the products, and of

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276. CAL. HEALTH & SAFETY CODE §§ 111791–111793.5 (West 2010); *California Safe Cosmetics Program*, CALIFORNIA DEP’T OF PUB. HEALTH, <http://www.cdph.ca.gov/programs/cosmetics/Pages/default.aspx> (last visited Sept. 20, 2011).

277. CAL. HEALTH & SAFETY CODE § 111792.

278. CAL. HEALTH & SAFETY CODE § 111792.5.

279. CAL. HEALTH & SAFETY CODE § 111793.

280. Assemb. B. 1879, 2008 Leg., Reg. Sess. (Cal. 2008).

281. S.B. 509, 2008 Leg., Reg. Sess. (Cal. 2008).

282. CAL. HEALTH & SAFETY CODE §§ 25251–25257 (West 2010); *California Green Chemistry Initiative*, CAL. DEP’T OF TOXIC SUBSTANCES CONTROL, <http://www.dtsc.ca.gov/pollutionprevention/greenchemistryinitiative/index.cfm> (last visited Sept. 20, 2011). For some of the policy background behind the Green Chemistry Initiative, see MICHAEL P. WILSON ET AL., CTRS. FOR OCCUPATIONAL & ENVTL. HEALTH, GREEN CHEMISTRY: CORNERSTONE TO A SUSTAINABLE CALIFORNIA (2008), available at [http://coeh.berkeley.edu/docs/news/green\\_chem\\_brief.pdf](http://coeh.berkeley.edu/docs/news/green_chem_brief.pdf); DEP’T OF TOXIC SUBSTANCES CONTROL, CALIFORNIA GREEN CHEMISTRY INITIATIVE: FINAL REPORT (2007), available at [http://www.dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiative/upload/GREEN\\_Chem.pdf](http://www.dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiative/upload/GREEN_Chem.pdf).

283. CAL. HEALTH & SAFETY CODE § 25252 (West 2010).

alternative products.<sup>284</sup> Under the statute, the DTSC must also adopt regulations specifying a range of regulatory responses that the Department may take following an analysis of a chemical and its alternatives, including labeling, banning, or not taking any action.<sup>285</sup> It also requires the DTSC to convene a “Green Ribbon Science Panel” of experts in the field to advise the Department,<sup>286</sup> and to create a “Toxics Information Clearinghouse,” a publicly accessible online database “for the collection, maintenance, and distribution of specific chemical hazard trait and environmental and toxicological end-point data.”<sup>287</sup> Implementation of the Green Chemistry Initiative has proven difficult and controversial, and the DTSC’s regulations remain under development.<sup>288</sup>

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284. *Id.* §§ 25252.5–25253. Under the statute, the Department shall take into account the following: “[p]roduct function or performance,” “useful life,” “[m]aterials and resource consumption,” “[w]ater conservation,” “[w]ater quality impacts,” “[a]ir emissions,” “[p]roduction, in-use, and transportation energy inputs,” “[e]nergy efficiency,” “[g]reenhouse gas emissions,” “[w]aste and end-of-life disposal,” “[p]ublic health impacts, including potential impacts to sensitive subpopulations, including infants and children,” “[e]nvironmental impacts,” and “[e]conomic impacts.” *Id.* § 25253(a)(2).

285. *Id.* § 25253. The actions the Department may take under the statute include the following: “[n]ot requiring any action,” “[i]mposing requirements to provide additional information,” “[i]mposing requirements on the labeling or other type of consumer product information,” “[i]mposing a restriction on the use of the chemical of concern,” “[p]rohibiting the use of the chemical of concern,” “[i]mposing requirements that control access to or limit exposure to the chemical of concern,” “[i]mposing requirements for the manufacturer to manage the product at the end of its useful life,” “[i]mposing a requirement to fund green chemistry challenge grants,” and “[a]ny other outcome the department determines accomplishes the requirements of” the statute. *Id.* § 25253(b).

286. *Id.* §§ 25254–25255.

287. *Id.* § 25256.

288. In September 2010, the Department released proposed regulations, which Governor Arnold Schwarzenegger approved; however, environmental organizations and other stakeholders assailed them as being insufficiently restrictive because they placed the burden of proof on the Department rather than on the chemical industry and because they left the Department exposed to possible litigation over unfavorable decisions. Michael Collins, *Schwarzenegger’s Chemical Romance*, L.A. WEEKLY, Dec. 9, 2010, available at <http://www.laweekly.com/2010-12-09/news/schwarzenegger-s-chemical-romance/>; CAL. DEP’T OF TOXIC SUBSTANCES CONTROL, SAFER CONSUMER PRODUCTS ALTERNATIVES, PROPOSED REGULATIONS (Sept. 2010), available at [http://www.dtsc.ca.gov/LawsRegsPolicies/upload/SCPA-Regs\\_APA-format-9-07-10-rev-9-12.pdf](http://www.dtsc.ca.gov/LawsRegsPolicies/upload/SCPA-Regs_APA-format-9-07-10-rev-9-12.pdf). In response, Governor Schwarzenegger and the Department rescinded the regulations and reconvened the Green Ribbon Panel. Michael Collins, *Arnold Schwarzenegger Backs Down on Gutting of California’s Green Chemistry Initiative*, L.A. WEEKLY, Dec. 27, 2010, available at [http://blogs.laweekly.com/informer/2010/12/arnold\\_wont\\_gut\\_chemicals\\_law.php](http://blogs.laweekly.com/informer/2010/12/arnold_wont_gut_chemicals_law.php); Letter from Linda S. Adams, Secretary for Environmental Protection, California Environmental Protection Agency, to Assembly Member

In September 2010, the New York State Department of Environmental Conservation (NYSDEC) took actions that may lead to substantial ingredient disclosure by household chemical product manufacturers.<sup>289</sup> The NYSDEC announced it would enforce a New

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Mike Feuer (Dec. 23, 2010), *available at* <http://www.dtsc.ca.gov/upload/GRSP-12-23-2010.pdf>. In February 2011, the DTSC requested public comment on the proposed regulations, and in June 2011 the Panel received peer review comments concerning the regulations. STATE OF CALIFORNIA ENVTL. PROTECTION AGENCY, OFFICE OF ENVTL. HEALTH HAZARD ASSESSMENT, COMMENTS ON PROPOSED HAZARD TRAITS REGULATION (Feb. 28, 2011), *available at* <http://www.oehha.ca.gov/multimedia/green/gc121710.html#comments>; STATE OF CALIFORNIA ENVTL. PROTECTION AGENCY, OFFICE OF ENVTL. HEALTH HAZARD ASSESSMENT, PEER REVIEW COMMENTS ON PROPOSED RULEMAKING (June 17, 2011), *available at* <http://www.oehha.ca.gov/multimedia/green/gc061711.html>. In July 2011, the DTSC, in conjunction with the California Office of Environmental Health Hazard Assessment, published a new set of regulations for public comment. OEHHA GREEN CHEMISTRY, JULY 2011, STATE OF CALIFORNIA ENVTL. PROTECTION AGENCY, OFFICE OF ENVTL. HEALTH HAZARD ASSESSMENT, <http://www.oehha.ca.gov/multimedia/green/gc072911.html> (last visited Sept. 20, 2011); STATE OF CALIFORNIA ENVTL. PROTECTION AGENCY, OFFICE OF ENVTL. HEALTH HAZARD ASSESSMENT, GREEN CHEMISTRY HAZARD TRAITS, MODIFIED TEXT OF PROPOSED REGULATIONS (July 29, 2011), *available at* <http://www.oehha.ca.gov/multimedia/green/pdf/072911RevisedGC.pdf>.

289. This decision of the New York State Department of Environmental Conservation may have been inspired in part by litigation brought by environmental groups. In 2009, Earthjustice, an environmental advocacy and litigation organization, and a coalition of other consumer and environmental advocacy organizations sued a range of household chemical manufacturers under a section of the Environmental Conservation Law of New York that had not been enforced since its passage in 1976. David Biello, *Earthjustice Wants Companies to List Chemicals in Household Cleaners*, SCIENTIFIC AMERICAN (Feb. 18, 2009), *available at* <http://www.scientificamerican.com/article.cfm?id=chemicals-in-household-cleaners>. In requiring the naming of more than just chemicals of “high concern” to state governments, this law, like the recent legislation in other states, would compel manufacturers to provide significantly more information to consumers. N.Y. COMP. CODES R. & REGS. tit. 6 § 659.6 (2010); *see infra* notes 289–98 and accompanying text. Success in the lawsuit would have impacted sales of household chemicals nationwide, since major chemical manufacturers would likely sell the same products in all states. Cleaning Product Chemical Reporting, EARTHJUSTICE, [http://www.earthjustice.org/our\\_work/cases/2009/cleaning-product-chemical-reporting.html](http://www.earthjustice.org/our_work/cases/2009/cleaning-product-chemical-reporting.html) (last visited Sept. 20, 2011). However, in 2010 the judge dismissed the case for lack of standing “without ruling on the merits” of the claims. *New York to Force Household Cleaner Giants to Reveal Chemical Ingredients*, EARTHJUSTICE, <http://earthjustice.org/news/press/2010/new-york-to-force-household-cleaner-giants-to-reveal-chemical-ingredients> (last visited Sept. 20, 2011); *Women’s Voices for the Earth, Inc. v. Procter & Gamble Co.*, No. 102035/2009 (N.Y. Sup. Ct. July 30, 2010) (unfiled disposition). In any event, this litigation would have been superseded by the decision of the State of New York Department of Environmental Conservation. Nonetheless, litigation under New York law or the laws of other states may remain a possible avenue by which to expand ingredient disclosure and labeling by household chemical manufacturers under other circumstances. For an argument in favor of the use of public nuisance litigation to compel the testing of chemicals, see Albert C. Lin, *Deciphering the Chemical Soup: Using Public Nuisance to Compel Chemical Testing*, 85 NOTRE DAME L. REV. 955 (2010); *see also* Noah

York law, not enforced since its passage in 1976, that gives the Department the authority to mandate the reporting of the ingredients of household cleansing products.<sup>290</sup> Under the law, all manufacturers of household cleansing products sold in the state of New York must provide “a list naming each ingredient which equals or exceeds five percent of the contents of the product by weight and specifying the content by weight of each ingredient to the nearest percent,” “a list naming each ingredient which does not equal or exceed five percent of the contents of the product by weight,” and “the nature and extent of investigations and research performed by or for the manufacturer concerning the effects on human health and environment of such product or such ingredients.”<sup>291</sup> While not requiring labeling,<sup>292</sup> the law would require cleansing product manufacturers to reveal significantly more information about the ingredients of their products than current federal law requires.<sup>293</sup> However, the range of products to which this law applies may be somewhat more limited.<sup>294</sup> The statute applies only to “cleansing products” and not to the full range of chemical products used in homes.<sup>295</sup> In September 2010, the NYSDEC requested various stakeholders, including “state officials, cleansing product manufacturers, and representatives of environmental non-government organizations,” to convene to discuss the implementation of the law.<sup>296</sup> If the NYSDEC exercises the full

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Sachs, *Blocked Pathways: Potential Legal Responses to Endocrine Disrupting Chemicals*, 24 COLUM. J. ENVTL. L. 289, 326–44 (1999).

290. N.Y. COMP. CODES R. & REGS. tit. 6, § 659.6 (2010).

291. *Id.* The regulation also requires reporting of “the amount of elemental phosphorus by weight as measured to the nearest one-tenth of one percent” and production of a “statement that the product does not contain nitrilotriacetic acid (NTA) in excess of a trace quantity.” *Id.*

292. While the statute does contain some labeling provisions, these appear to relate solely to the quantity of phosphorus in the products. N.Y. COMP. CODES R. & REGS. tit. 6, § 659.4 (2010).

293. *New York to Force Household Cleaner Giants to Reveal Chemical Ingredients*, EARTHJUSTICE, *supra* note 289.

294. *Id.*

295. *Id.*

296. Letter from Alexander B. Grannis, Commissioner, Department of Environmental Conservation, State of New York, to Deborah Goldberg, EARTHJUSTICE (Sept. 3, 2010), available at [http://earthjustice.org/sites/default/files/files/DEC\\_letter\\_9\\_9.pdf](http://earthjustice.org/sites/default/files/files/DEC_letter_9_9.pdf). In March 2011, the Department released a draft proposal indicating that it would require reporting of all ingredients present in more than “trace amounts” and would require ingredient lists to indicate whether each ingredient was “an asthmagen, carcinogen, reproductive toxin, mutagen,



range of its authority under the statute, the law could affect sales of cleansing products nationwide, since major chemical manufacturers generally sell the same products in every state.<sup>297</sup> However, the law would not provide such information at the point of purchase, as a labeling scheme would, nor would it cover the full range of products, ingredients, and hazards that present concern.<sup>298</sup>

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persistent, bioaccumulative toxin, ozone-depleting compound or chemical of concern.” NEW YORK STATE DEPARTMENT OF ENVIRONMENTAL CONSERVATION, DEC DRAFT PROPOSAL (2011), available at [http://earthjustice.org/sites/default/files/DEC\\_Draft\\_Proposal.pdf](http://earthjustice.org/sites/default/files/DEC_Draft_Proposal.pdf). The Department would also “request that manufacturers post information on their websites regarding the nature and extent of investigations and research performed by or for the manufacturer concerning the effects on human health and the environment of their products or the chemical ingredients of such products.” *Id.* While stakeholders have met and submitted comments regarding the Department’s proposed action, the Department has not yet enforced the law. Press Release, Environmental Advocates of New York, Groups Applaud Progress on Cleaning Product Chemical Right-To-Know Effort, Submit Response to State Proposal (Mar. 2, 2011), available at [http://www.eany.org/index.php?option=com\\_content&view=article&id=272:groups-applaud-progress-on-cleaning-product-chemical-right-to-know-effort](http://www.eany.org/index.php?option=com_content&view=article&id=272:groups-applaud-progress-on-cleaning-product-chemical-right-to-know-effort); Press Release, ISSA, ISSA Comments on New York Ingredient Disclosure Proposal (Mar. 2, 2011), available at <http://www.issa.com/?m=news&event=view&type=17&id=4072>. A coalition of forty-one environmental organizations submitted comments, as did industry trade groups. Letter from Deborah Goldberg, Managing Attorney, EARTHJUSTICE, to Joseph Martens, Acting Commissioner, N.Y. State Dep’t of Env’tl. Conservation (Feb. 28, 2011), available at [http://media40.wnyc.net/media/resources/2011/Mar/03/NGO\\_response.pdf](http://media40.wnyc.net/media/resources/2011/Mar/03/NGO_response.pdf) (commenting on behalf of 44 environmental organizations); Letter from Dennis Griesing, *supra* note 275 (commenting on behalf of chemical industry trade association); Letter from Sean R. Moore, Director, State Affairs—East Region, & D. Douglas Fratz, Vice President, Scientific & Technical Affairs, Consumer Speciality Products Association to Elizabeth E. Meer, Special Assistant, COMMISSIONER’S POLICY OFFICE, N.Y. STATE DEP’T OF ENVTL. CONSERVATION (Mar. 1, 2011), available at [http://media40.wnyc.net/media/resources/2011/Mar/04/CSPA\\_Comments\\_on\\_NYSDEC\\_Ingredient\\_Disclosure\\_Proposal\\_03\\_01\\_2011.pdf](http://media40.wnyc.net/media/resources/2011/Mar/04/CSPA_Comments_on_NYSDEC_Ingredient_Disclosure_Proposal_03_01_2011.pdf) (same).

297. *New York to Force Household Cleaner Giants to Reveal Chemical Ingredients*, *supra* note 289.

298. While a complete discussion is beyond the scope of this note, international regulation may also affect the labeling and disclosure of household chemical ingredients. In particular, the European Union recently instituted Regulation No. 1907/2006 concerning the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH). Commission Regulation 1907/2006, Registration, Evaluation, Authorisation, and Restriction of Chemicals, 2006 O.J. (L 396), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=oj:l:2006:396:0001:0849:en:pdf>. REACH requires registration of chemical products with the European Chemicals Agency, a process which involves disclosure of a variety of information concerning “properties, uses and safe ways of handling” chemicals. EUROPEAN COMM’N, ENVIRONMENT FACT SHEET: REACH—A NEW CHEMICALS POLICY FOR THE EU 3 (2006), available at <http://ec.europa.eu/environment/pubs/pdf/factsheets/reach.pdf>; EUROPEAN CHEMICALS AGENCY, [http://www.echa.europa.eu/home\\_en.asp](http://www.echa.europa.eu/home_en.asp) (last visited Sept. 20, 2011). However, “some information will be published on the Agency’s web site, some information will generally be kept confidential, and some may be made available on request.” EUROPEAN COMM’N, REACH IN BRIEF 15 (2007),

The regulatory efforts in California and New York represent particularly significant examples of state attempts to mandate household chemical ingredient disclosure due to the size of their markets and the extent of the regulations involved. However, those states are hardly unique in their efforts, and state regulation presents possible models, opportunities, and conflicts that decisionmakers may have to take into account when developing federal regulations.<sup>299</sup>

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available at [http://ec.europa.eu/environment/chemicals/reach/pdf/2007\\_02\\_reach\\_in\\_brief.pdf](http://ec.europa.eu/environment/chemicals/reach/pdf/2007_02_reach_in_brief.pdf). REACH does not provide for labeling beyond that required under previous directives. *Classification & Labeling*, EUROPEAN CHEMICALS AGENCY, [http://guidance.echa.europa.eu/classification\\_label\\_en.htm](http://guidance.echa.europa.eu/classification_label_en.htm) (last visited Sept. 20, 2011). The Agency and member states evaluate the producer's submission, and the results can lead to restrictions on the distribution of the products, including a potential ban. *REACH Processes*, EUROPEAN CHEMICALS AGENCY, [http://guidance.echa.europa.eu/reach\\_processes\\_en.htm](http://guidance.echa.europa.eu/reach_processes_en.htm) (last visited Sept. 20, 2011). The producers must obtain authorization to employ chemicals of high concern. *Id.* Although this does not equate to a full point-of-purchase labeling system, the European Commission expects that the information gathered, and the evaluation and authorization process, will help reduce the environmental damage and negative health effects of certain chemicals. EUROPEAN COMMISSION, REACH IN BRIEF, *supra*, at 15–16. REACH has already impacted the way producers manufacture their products and is the model for some state legislation. MARK SCHAPIRO, EXPOSED: THE TOXIC CHEMISTRY OF EVERYDAY PRODUCTS AND WHAT'S AT STAKE FOR AMERICAN POWER 187–88 (2007).

299. In addition to the recent regulatory actions in California and New York, numerous other provisions of recent state legislation addressing toxic chemicals in household products suggest that a new trend may be developing. LeBel, *supra* note 260, at 71. For example, in Massachusetts, the Safer Alternatives Bill seeks to replace toxic chemicals with safer alternatives where feasible and would fund consumer education programs about “toxic substances.” An Act for a Competitive Economy through Safer Alternatives to Toxic Chemicals, S. 397, 2011 Leg., 187th Sess. (Mass. 2011); An Act for a Competitive Economy through Safer Alternatives to Toxic Chemicals, H. 1136, 2011 Leg., 187th Sess. (Mass. 2011); ALLIANCE FOR A HEALTHY TOMORROW, THE SAFER ALTERNATIVES BILL: AN ACT FOR A COMPETITIVE ECONOMY THROUGH SAFER ALTERNATIVES TO TOXIC CHEMICALS 2 (2011), available at [http://cdn.publicinterestnetwork.org/assets/LaPKh4Y6dtJz-VqHbNUC\\_A/safe-products-made-safely-10-sa-bill-fact-sheet-1092.pdf](http://cdn.publicinterestnetwork.org/assets/LaPKh4Y6dtJz-VqHbNUC_A/safe-products-made-safely-10-sa-bill-fact-sheet-1092.pdf). Massachusetts has already implemented the 1989 Toxics Use Reduction Act, a law focused on reducing toxic chemical use by companies using large quantities of them. MASS. GEN. LAWS ch. 21I, §§ 1–23 (2010); *Toxics Use Reduction Act (TURA)*, MASS. DEP'T OF ENVTL. PROTECTION, <http://www.mass.gov/dep/toxics/toxicus.htm> (last visited Sept. 20, 2011) (explaining the legislation's requirements). In Washington, the Children's Safe Products Act, enacted in 2008, prohibits the sale of children's products containing a variety of chemicals and requires the state Department of Ecology to identify other chemicals that could pose health concerns. WASH. REV. CODE § 70.240.010-060 (2010); CSPA—Waste 2 Resources, State of Washington Dep't of Ecology, <http://www.ecy.wa.gov/programs/swfa/cspa/> (last visited Sept. 20, 2011) (explaining legislation's requirements). In Michigan, legislation with the same name, the Children's Safe Products Act, passed the Michigan House of Representatives in May 2009 and would require chemical products manufacturers to disclose whether or not their products contain certain “chemicals of highest concern.” H.B. 4763-4769, 95th Leg., Reg. Sess. (Mich. 2009). The bill failed to pass the

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Michigan Senate, but legislators plan to reintroduce it in 2011. Press Release, Michigan Network for Children's Envtl. Health, State Senator to Introduce Bill that Helps Protect Michigan Kids from Toxic Chemicals in Children's Products (Jan. 19, 2011), *available at* [http://www.ecocenter.org/press/Jan19\\_PressRelease-1.pdf](http://www.ecocenter.org/press/Jan19_PressRelease-1.pdf). In Maine, the Kid Safe Products Act, enacted in 2008, requires the state Department of Environmental Protection to publish a list of "chemicals of high concern" and to identify "priority chemicals" from that list, and compels manufacturers of children's products to disclose to the Department any of their products that contain those priority chemicals. ME. REV. STAT. ANN. tit. 38, §§ 1691–1699 (2009); *see also* DEP'T OF ENVTL. PROTECTION, STATE OF MAINE, CHEMICALS OF HIGH CONCERN LIST (July 17, 2009), *available at* [http://www.maine.gov/dep/oc/safechem/highconcern/DEP.CHC.web.short\\_list\\_7\\_16\\_09.pdf](http://www.maine.gov/dep/oc/safechem/highconcern/DEP.CHC.web.short_list_7_16_09.pdf). The Act also permits the Department to ban the sale of children's products if sale of the product would expose "children and vulnerable populations to the priority chemical" and "[o]ne or more safer alternatives to the priority chemical are available at a comparable cost." tit. 38, § 1696. In Minnesota, the Toxic-Free Kids Act, enacted in May 2009, requires the state Department of Health to publish and regularly revise a list of "chemicals of high concern," identify priority chemicals from that list, and publish lists of those priority chemicals "in the State Register and on the department's Internet Web site." MINN. STAT. § 116.9401-116.9407 (2009); *Chemicals of High Concern and Priority Chemicals*, MINN. DEP'T OF HEALTH, STATE OF MINNESOTA, <http://www.health.state.mn.us/divs/eh/hazardous/topics/toxfreekids/index.html> (last visited Sept. 20, 2011). In 2010, Connecticut passed legislation establishing a Chemical Innovations Institute at the University of Connecticut Health Center that will "foster green job growth and safer workplaces [by] encouraging clean technology innovation and [the] utilization of green chemistry" and "provide assistance to businesses, state agencies and nonprofit organizations that seek to utilize alternatives" to harmful chemicals. CONN. GEN. STAT. § 22a-903 (2011); Chemical Innovations Institute, UNIV. OF CONN. HEALTH CTR., [http://oehc.uhc.edu/centers\\_CII.asp](http://oehc.uhc.edu/centers_CII.asp) (last visited Sept. 20, 2011). These state laws represent only a few of the more significant state laws and are only a sample of a complex and rapidly changing area of law. *See* Press Release, Safer Chemicals, Healthy Families, 30 States Nationwide to Announce Upcoming Bills to Protect Kids and Families from Toxic Chemicals on Wed. Jan 19 (Jan. 18, 2011), *available at* <http://www.saferchemicals.org/2011/01/30-states-nationwide-to-announce-upcoming-bills-to-protect-kids-and-families-from-toxic-chemicals-on.html> (claiming that "on Wednesday, January 19, legislators and advocates in thirty states across the country and the District of Columbia will announce legislation aimed at protecting children and families from harmful chemicals" and that "18 state legislatures have already passed 71 chemical safety laws in the last eight years."); *see also* MIKE BELLIVEAU, SAFER CHEMICALS, HEALTHY FAMILIES & SAFER STATES, HEALTHY STATES: PROTECTING FAMILIES FROM TOXIC CHEMICALS WHILE CONGRESS LAGS BEHIND 12 (2010), *available at* <http://www.saferchemicals.org/PDF/reports/HealthyStates.pdf>. The Safer States coalition is a network of state environmental organizations pursuing the reform of state chemicals regulation. *About Safer States*, SAFER STATES, <http://www.saferstates.com/about/index.html> (last visited Sept. 20, 2011). While not specifically providing for any labeling or warning statements on product packaging, these laws indicate an increased willingness in state legislatures to regulate household chemical products and may put pressure on the federal government to pass its own regulations.

Recently, the environmental protection agencies of California, Connecticut, Massachusetts, Michigan, Minnesota, New Jersey, New York, Oregon, Washington, and the Portland, Oregon metropolitan area formed the Interstate Chemicals Clearinghouse in an attempt to coordinate chemical regulation efforts. NORTHEAST WASTE MGMT. OFFICIALS' ASS'N, STATE AND LOCAL GOVERNMENTS FORM INTERSTATE CHEMICALS CLEARINGHOUSE TO PROMOTE TOXICS REDUCTION (2011), *available at* <http://www.newmoa.org/prevention/ic2/about/pressrelease.pdf>.

#### IV. HOUSEHOLD CHEMICAL INGREDIENTS POSING HEALTH AND ENVIRONMENTAL CONCERNS

The ingredients of many household chemical products may present a wide array of health and environmental concerns for those who purchase and use them. The following selection of common ingredients should not be considered a comprehensive assessment of household chemical health and environmental risks, nor is it a comprehensive assessment of the potential risks of any of the individual chemicals included. However, it should provide a solid introduction to the kinds of health and environmental issues that exposure to these chemicals may cause. As their hazards have become more apparent, manufacturers have reduced their use of some of these chemicals; however, most chemicals remain untested, and their potential effects insufficiently evaluated.<sup>300</sup>

##### A. Health Effects

###### 1. Formaldehyde

Perhaps better known for its role in preserving corpses, formaldehyde appears in numerous household chemical products, including cleaning products, cosmetics, and paints.<sup>301</sup> In 2011, the

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The Clearinghouse enables agencies to improve efficiency, to share information and regulation strategies, and to support various chemical information, training, and management efforts. NORTHEAST WASTE MANAGEMENT OFFICIALS' ASSOCIATION, WHAT IS THE INTERSTATE CHEMICALS CLEARINGHOUSE (IC2)?, *available at* <http://www.newmoa.org/prevention/ic2/about/IC2factsheet.pdf>. The development of the Clearinghouse remains ongoing and its effectiveness remains unclear. KEN GEISER & TERRI GOLDBERG, ENVISIONING THE FUTURE OF THE INTERSTATE CHEMICALS CLEARINGHOUSE (2010), *available at* [http://www.newmoa.org/prevention/webconferences/plancom/IC2\\_Future.pdf](http://www.newmoa.org/prevention/webconferences/plancom/IC2_Future.pdf).

300. *See infra* note 473 and accompanying text.

301. Many household chemical products (including furniture polishes, paints, car cleaners, powder and liquid cleaners, hair care products, nail care products, and hand soaps, among other products) contain formaldehyde as either an ingredient or an impurity. *See generally* SKIN DEEP COSMETICS DATABASE, ENVTL. WORKING GRP., <http://www.ewg.org/skindeep/search.php?query=formaldehyde&h=Go> (last visited Sept. 20, 2010) [hereinafter *Skin Deep*]; *Chemical Profile for Formaldehyde*, SCORECARD: THE POLLUTION INFORMATION SITE, [http://scorecard.goodguide.com/chemical-profiles/summary.tcl?edf\\_substance\\_id=50%2d00%2d0](http://scorecard.goodguide.com/chemical-profiles/summary.tcl?edf_substance_id=50%2d00%2d0) (last visited Sept. 20, 2010); AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY, U.S. DEPT. OF HEALTH AND HUMAN SERVICES, TOXFAQS: FORMALDEHYDE 1 (1999), *available at* <http://www.atsdr.cdc.gov/tfacts111.pdf>. Consumer groups have raised particular concerns about the

U.S. Department of Health and Human Services officially determined that “[f]ormaldehyde is known to be a human carcinogen.”<sup>302</sup> The

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use of formaldehyde, along with phthalates and toluene, as an ingredient in nail polishes. ALEXANDRA GORMAN & PHILIP O’CONNOR, WOMEN’S VOICES FOR THE EARTH, GLOSSED OVER: HEALTH HAZARDS ASSOCIATED WITH TOXIC EXPOSURE IN NAIL SALONS (2007), available at [http://www.womensvoices.org/wp-content/uploads/2010/06/Glossed\\_Over.pdf](http://www.womensvoices.org/wp-content/uploads/2010/06/Glossed_Over.pdf); NAT’L HEALTHY NAIL SALON ALLIANCE, PHASING OUT THE “TOXIC TRIO”: A REVIEW OF POPULAR NAIL POLISH BRANDS (2009), available at [http://womenandenvironment.onenw.org/campaignsandprograms/SafeCosmetics/campaignsandprograms/SafeCosmetics/nail\\_report.pdf](http://womenandenvironment.onenw.org/campaignsandprograms/SafeCosmetics/campaignsandprograms/SafeCosmetics/nail_report.pdf). A 2009 study even found formaldehyde in children’s bath products. CAMPAIGN FOR SAFE COSMETICS, NO MORE TOXIC TUB: GETTING CONTAMINANTS OUT OF CHILDREN’S BATH AND PERSONAL CARE PRODUCTS 4 (2009), available at [http://www.safecosmetics.org/downloads/NoMoreToxicTub\\_Mar09Report.pdf](http://www.safecosmetics.org/downloads/NoMoreToxicTub_Mar09Report.pdf).

In 2010, a controversy began that centered around a new hair straightening product called “Brazilian Blowout.” MSNBC.com, *Hazardous for Health? Roots of Brazilian Blowout* (Feb. 23, 2011), available at <http://today.msnbc.msn.com/id/41742315/ns/today-style/t/hazardous-health-roots-brazilian-blowout/>. Government public health services and consumer organizations found that the product contained up to 12% formaldehyde. HEALTH CANADA, BRAZILIAN BLOWOUT CONTAINS FORMALDEHYDE (Oct. 7, 2010), available at [http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/\\_2010/2010\\_167-eng.php](http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2010/2010_167-eng.php) (Canadian public health advisory stating that Brazilian Blowout contained 12% formaldehyde); MSNBC.com, *supra*. As public health organizations investigated Brazilian Blowout and other hair straightening products, the widespread use of substantial quantities of formaldehyde in these products became apparent, and a variety of other public health authorities issued alerts. MSNBC.com, *supra*. California sued the manufacturer under the California Safe Cosmetics Act of 2005 in November 2010, OSHA issued a hazard warning in April 2011, and the FDA issued a warning letter to the manufacturer in August 2011. Brian Walsh, *Warning: Getting Your Hair Straightened Could Endanger Your Health*, TIME, Apr. 13, 2011, available at <http://healthland.time.com/2011/04/13/warning-getting-your-hair-straightened-could-be-hazardous-to-your-health/>; OCCUPATIONAL SAFETY & HEALTH ADMIN., U.S. DEPT. OF LABOR, HAZARD ALERT: HAIR SMOOTHING PRODUCTS THAT COULD RELEASE FORMALDEHYDE (Apr. 2011), available at [http://www.osha.gov/SLTC/formaldehyde/hazard\\_alert.pdf](http://www.osha.gov/SLTC/formaldehyde/hazard_alert.pdf); FOOD & DRUG ADMIN., WARNING LETTER: GIG, LLC DBA BRAZILIAN BLOWOUT (Aug. 22, 2011), available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm270809.htm>. An EWG study found that numerous other hair straightening products contained substantial amounts of formaldehyde, despite claims indicating otherwise. ENVTL. WORKING GROUP, FLAT-OUT RISKY: HAIR STRAIGHTENER MAKERS AND SALONS COVER UP DANGERS (Apr. 12, 2011), available at <http://www.ewg.org/hair-straighteners/>. Public health agencies have reached similar conclusions. See, e.g., HEALTH CANADA, SEVERAL PROFESSIONAL HAIR SMOOTHING SOLUTIONS CONTAIN FORMALDEHYDE (Dec. 10, 2010), available at [http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/\\_2010/2010\\_222-eng.php](http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2010/2010_222-eng.php); OREGON OCCUPATIONAL SAFETY & HEALTH DIV., “KERATIN-BASED” HAIR SMOOTHING PRODUCTS AND THE PRESENCE OF FORMALDEHYDE (Oct. 29, 2010), available at [http://orosh.org/pdf/Final\\_Hair\\_Smoothing\\_Report.pdf](http://orosh.org/pdf/Final_Hair_Smoothing_Report.pdf). The experience with hair straightening products highlighted the gaps in our present knowledge of the composition of cosmetic products, and in the government’s current capacity to regulate them.

302. DEP’T OF HEALTH & HUMAN SERVS., REPORT ON CARCINOGENS, TWELFTH EDITION (2011), available at <http://ntp.niehs.nih.gov/ntp/roc/twelfth/profiles/Formaldehyde.pdf>. However, the DHHS had evidence of formaldehyde’s potential as a human carcinogen at least as early as 1981, when the agency labeled it as “reasonably anticipated to be a human

World Health Organization has also determined that formaldehyde is a carcinogen,<sup>303</sup> and other countries have banned or limited its use in various consumer products.<sup>304</sup> Recent studies indicate that it may also function as a neurotoxin<sup>305</sup> and contribute to asthma,<sup>306</sup> among a variety of other potential negative health conditions.<sup>307</sup> The EPA recently produced a draft inhalation toxicological review of formaldehyde that exhaustively detailed studies performed on the chemical.<sup>308</sup> The study found that “[f]ormaldehyde is [c]arcinogenic to [h]umans by the [i]nhalation [r]oute of [e]xposure.”<sup>309</sup> It also

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carcinogen.” *Id.*; NAT’L INST. FOR OCCUPATIONAL SAFETY & HEALTH, U.S. DEP’T OF HEALTH & HUMAN SERVS., CURRENT INTELLIGENCE BULLETIN 34: FORMALDEHYDE: EVIDENCE OF CARCINOGENITY (1981), available at [http://www.cdc.gov/niosh/81111\\_34.html](http://www.cdc.gov/niosh/81111_34.html). Likewise, the EPA classified formaldehyde as a “probable human carcinogen” as early as 1987. OFFICE OF AIR AND RADIATION, ENVTL. PROTECTION AGENCY, REPORT TO CONGRESS ON INDOOR AIR QUALITY, VOLUME II: ASSESSMENT AND CONTROL OF INDOOR AIR POLLUTION (1989), available at <http://nepis.epa.gov/Exe/ZyNET.exe/9100LMBU.TXT>.

303. INT’L AGENCY FOR RESEARCH ON CANCER, WORLD HEALTH ORG., 88 IARC MONOGRAPHS ON THE EVALUATION OF CARCINOGENIC RISKS TO HUMANS 93, 280 (2006), available at <http://monographs.iarc.fr/ENG/Monographs/vol88/mono88.pdf>.

304. The European Union limits the use of formaldehyde in cosmetics and requires the use of a warning reading “contains formaldehyde” on the labels of products that contain more than .05% formaldehyde. Council Directive 76/768, 1976 O.J. (L 262) (EC), available at <http://eur-lex.europa.eu/LexUriServ/site/en/consleg/1976/L/01976L0768-20060809-en.pdf>; Opinion Concerning a Clarification on the Formaldehyde and Para-Formaldehyde Entry in Directive 76/768/EEC on Cosmetic Products, COM (2002) SCCNFP/587/02, final (Dec. 17, 2002). Other countries, including Canada, Japan, and Sweden, have banned or limited the use of formaldehyde in various consumer chemical products. A.S. Polati, F. Gosett, & M.C. Gennaro, *Preservatives in Cosmetics Analytical Methods*, in ANALYSIS OF COSMETIC PRODUCTS 215 (Amparo Salvador & Alberto Chisvert eds., 2007); *Cosmetic Ingredient Hotlist*, HEALTH CANADA, [http://www.hc-sc.gc.ca/cps-spc/cosmet-person/indust/hot-list-critique/hotlist-liste\\_dl-eng.php](http://www.hc-sc.gc.ca/cps-spc/cosmet-person/indust/hot-list-critique/hotlist-liste_dl-eng.php) (last visited Sept. 20, 2011).

305. Ahmet Songur et al., *The Toxic Effects of Formaldehyde on the Nervous System*, 203 REVS. ENVTL. CONTAMINATION & TOXICOLOGY 105 (2010); Fathi A. Malek et al., *Effects of a Single Inhalative Exposure to Formaldehyde on the Open Field Behavior of Mice*, 207 INT’L J. HYGIENE & ENVTL. HEALTH 151 (2004).

306. Gerald McGwin et al., *Formaldehyde Exposure and Asthma in Children: A Systematic Review*, 118 ENVTL. HEALTH PERSP. 313 (2010); Krassi Rumchev et al., *Domestic Exposure to Formaldehyde Significantly Increases the Risk of Asthma in Young Children*, 20 EUR. RESPIRATORY J. 403 (2002).

307. *CHE Toxicant and Disease Database*, COLLABORATIVE ON HEALTH AND THE ENVIRONMENT, <http://www.healthandenvironment.org/tddb/contam/2371> (last visited Sept. 20, 2011).

308. ENVTL. PROT. AGENCY, TOXICOLOGICAL REVIEW OF FORMALDEHYDE—INHALATION ASSESSMENT (2010), available at [http://oaspub.epa.gov/eims/eimscomm.getfile?p\\_download\\_id=49703](http://oaspub.epa.gov/eims/eimscomm.getfile?p_download_id=49703).

309. *Id.* at 6-45 to -46.

documented additional concerns regarding “sensory irritation of the eyes, nose, and throat,” “upper respiratory tract pathology,” “pulmonary function,” “asthma and atopy,” “neurologic and behavioral toxicity,” “reproductive and developmental toxicity,” and “immunological toxicity.”<sup>310</sup>

## 2. Phthalates

The term phthalates refers to a group of chemicals used in a wide array of consumer products, including household chemicals such as cosmetics, insecticides, and cleaning products.<sup>311</sup> Studies indicate that phthalates may act as endocrine disruptors and may affect the human reproductive system, particularly in infants.<sup>312</sup> Phthalates may also affect the thyroid<sup>313</sup> and may cause cancer,<sup>314</sup> birth and developmental

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310. *Id.*

311. Phthalates appear in soaps, sunscreens, nail care products, hair sprays, shampoos, detergents, fragrances, bath oils, deodorants, moisturizers, mascaras, eyeliners, insecticides, insect repellents, adhesives, lubricants, and other household chemical products. Ted Schettler, *Human Exposure to Phthalates Via Consumer Products*, 29 INT’L J. ANDROLOGY 134, 136–37 (2006); *Phthalates*, ENVTL. WORKING GRP., <http://www.ewg.org/chemindex/term/480> (last visited Sept. 20, 2011); *Skin Deep*, *supra* note 301; Jean Hubinger & Don Havery, *Analysis of Consumer Cosmetic Products for Phthalate Esters*, 57 J. COSMETIC SCI. 127 (2006); RUUD J.B. PETERS, TNO ENV’T & GEOSCIS., PHTHALATES AND ARTIFICIAL MUSKS IN PERFUMES 3 (2005), available at <http://www.greenpeace.org/raw/content/international/press/reports/phthalates-and-artificial-musk.pdf>.

312. See, e.g., Russ Hauser et al., *DNA Damage in Human Sperm is Related to Urinary Levels of Phthalate Monoester and Oxidative Metabolites*, 22 HUMAN REPROD. 688 (2006); Katharina M. Main et al., *Human Breast Milk Contamination with Phthalates and Alterations of Endogenous Reproductive Hormones in Infants Three Months of Age*, 114 ENVTL. HEALTH PERSP. 270 (2006); Shanna H. Swan et al., *Decrease in Anogenital Distance Among Male Infants with Prenatal Phthalate Exposure*, 113 ENVTL. HEALTH PERSP. 1056 (2005); Tara Lovekamp-Swan & Barbara J. Davis, *Mechanisms of Phthalate Ester Toxicity in the Female Reproductive System*, 111 ENVTL. HEALTH PERSP. 139 (2003); Susan M. Duty et al., *Phthalate Exposure and Human Semen Parameters*, 14 EPIDEMIOLOGY 268 (2003).

313. See, e.g., John D. Meeker et al., *Di(2-ethylhexyl) Phthalate Metabolites May Alter Thyroid Hormone Levels in Men*, 115 ENVTL. HEALTH PERSP. 115 (2007); Po-Chin Huang et al., *Associations between Urinary Phthalate Monoesters and Thyroid Hormones in Pregnant Women*, 22 HUMAN REPROD. 2715 (2007).

314. See, e.g., Norbert H. Kleinsasser et al., *Genotoxicity of Di-Butyl-Phthalate and Di-Iso-Butyl-Phthalate in Human Lymphocytes and Mucosal Cells*, 21 TERATOGENESIS, CARCINOGENESIS, & MUTAGENESIS 189 (2001); Lizbeth López-Carrillo, *Exposure to Phthalates and Breast Cancer Risk in Northern Mexico*, 118 ENVTL. HEALTH PERSP. 529 (2010).

defects,<sup>315</sup> obesity and insulin resistance,<sup>316</sup> and shorter pregnancies,<sup>317</sup> among other possibilities.<sup>318</sup> Toxicity can vary, however, depending on the specific phthalate ester included in the product.<sup>319</sup>

### 3. Triclosan

Triclosan appears as an antibacterial and antifungal agent in a wide variety of personal care and cleaning products.<sup>320</sup> Studies have

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315. See, e.g., Christina M. Carruthers & Paul M. D. Foster, *Critical Window of Male Reproductive Tract Development in Rats Following Gestational Exposure to Di-n-butyl Phthalate*, 74 BIRTH DEFECTS RES. 277 (2005); G. Lottrup et al., *Possible Impact of Phthalates on Infant Reproductive Health*, 29 INT'L J. ANDROLOGY 172 (2006); S.H. Swan et al., *Prenatal Phthalate Exposure and Reduced Masculine Play in Boys*, 33 INT'L J. ANDROLOGY 259 (2010); Soo-Churl Cho et al., *Relationship between Environmental Phthalate Exposure and the Intelligence of School-Age Children*, 118 ENVTL. HEALTH PERSP. 1027, 1030 (2010); Stephanie M. Engel, et al., *Prenatal Phthalate Exposure Is Associated with Childhood Behavior and Executive Functioning*, 118 ENVTL. HEALTH PERSP. 565 (2010); Katharina M. Main et al., *supra* note 312; Mary S. Wolff et al., *Investigation of Relationships Between Urinary Biomarkers of Phytoestrogens, Phthalates, and Phenols and Pubertal Stages in Girls*, 118 ENVTL. HEALTH PERSP. 1039 (2010). Due to concerns regarding the effects of phthalates on children, some countries and American states, including California, have banned the use of phthalates in children's products. CAL. HEALTH & SAFETY CODE, § 108937 (West Supp. 2011); James Bothwell, *Toy Story: Timeout for Phthalates*, 39 MCGEORGE L. REV. 551, 552 (2008).

316. Richard W. Stahlhut et al., *Concentrations of Urinary Phthalate Metabolites Are Associated with Increased Waist Circumference and Insulin Resistance in Adult U.S. Males*, 115 ENVTL. HEALTH PERSP. 876, 880 (2007).

317. Giuseppe Latini et al., *In Utero Exposure to Di-(2-ethylhexyl)phthalate and Duration of Human Pregnancy*, 111 ENVTL. HEALTH PERSP. 1783, 1784 (2003).

318. See, e.g., Carl-Gustaf Bornehag et al., *The Association Between Asthma and Allergic Symptoms in Children and Phthalates in House Dust: A Nested Case-Control Study*, 112 ENVTL. HEALTH PERSP. 1393 (2004); Ursel Heudorf et al., *Phthalates: Toxicology and Exposure*, 210 INT'L J. HYGIENE & ENVTL. HEALTH 623 (2007); HEATHER SARANTIS ET AL., ENVTL. WORKING GRP., NOT SO SEXY: THE HEALTH RISKS OF SECRET CHEMICALS IN FRAGRANCE 21–22 (2010), available at [http://www.ewg.org/files/SafeCosmetics\\_FragranceRpt.pdf](http://www.ewg.org/files/SafeCosmetics_FragranceRpt.pdf); Shanna H. Swan, *Environmental Phthalate Exposure in Relation to Reproductive Outcomes and Other Health Endpoints in Humans*, 108 ENVTL. RES. 177 (2008); *Phthalates and Cumulative Risk Assessment: The Task Ahead*, Committee on the Health Risks of Phthalates, Nat'l Res. Council of the Nat'l Acads., 111–23 (2008), available at <http://www.nap.edu/catalog/12528.html>.

319. *Id.*

320. Triclosan appears in soaps, deodorants, moisturizers, lipsticks, shampoos, toothpastes, detergents, fabric softeners, floor waxes, carpet shampoos, household cleaners, and pesticides. Aviva Glaser, *The Ubiquitous Triclosan: A Common Antibacterial Agent Exposed*, 24 PESTICIDES & YOU 12, 12 (2004); *Skin Deep*, *supra* note 301; *Triclosan in Your Home*, ENVTL. WORKING GRP., <http://www.ewg.org/node/26752> (last visited Sept. 20, 2011); Chemical Profile for Triclosan, SCORECARD: THE POLLUTION INFORMATION SITE, <http://www.scorecard.org/>



indicated that triclosan may impact thyroid hormone production<sup>321</sup> and have estrogenic and androgenic effects on human breast cancer cells,<sup>322</sup> among other possible effects.<sup>323</sup> Studies also indicate that the ubiquitous use of triclosan may contribute to antimicrobial and antibiotic resistance.<sup>324</sup>

#### 4. Perfluorinated Compounds (PFCs)

Perfluorinated compounds comprise a group of chemicals, including perfluorooctanoic acid (PFOA), the main component of polytetrafluoroethylene (PTFE) (the principal ingredient in Teflon), that appear in a wide range of household chemical products.<sup>325</sup> Studies have connected PFCs with cancer,<sup>326</sup> low birth weight,<sup>327</sup>

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chemical-profiles/summary.tcl?edf\_substance\_id=3380%2d34%2d5#use\_profile (last visited Sept. 20, 2011).

321. See, e.g., Kevin M. Crofton et al., *Short-term In Vivo Exposure to the Water Contaminant Triclosan: Evidence for Disruption of Thyroxine*, 24 ENVTL. TOXICOLOGY & PHARMACOLOGY 194, 196 (2007); Nik Veldhoen et al., *The Bactericidal Agent Triclosan Modulates Thyroid Hormone-Associated Gene Expression and Disrupts Postembryonic Anuran Development*, 80 AQUATIC TOXICOLOGY 217, 224–25 (2006); Leah M. Zorilla et al., *The Effects of Triclosan on Puberty and Thyroid Hormones in Male Wistar Rats*, 107 TOXICOLOGICAL SCI. 56 (2008).

322. See, e.g., R. H. Gee et al., *Oestrogenic and Androgenic Activity of Triclosan in Breast Cancer Cells*, 28 J. APPLIED TOXICOLOGY 78, 87–88 (2008).

323. *Pesticide in Soap, Toothpaste and Breast Milk—Is It Kid-Safe?*, ENVTL. WORKING GRP. (July 17, 2008), available at <http://www.ewg.org/reports/triclosan>.

324. See, e.g., Allison E. Aiello et al., *Consumer Antibacterial Soaps: Effective or Just Risky?*, 45 CLINICAL INFECTIOUS DISEASES S137, S146 (2007); Stuart B. Levy, *Antibacterial Household Products: Cause for Concern*, 7 EMERGING INFECTIOUS DISEASES 512 (2001); Mark A. Webber et al., *Triclosan Resistance in Salmonella Enterica Serovar Typhimurium*, 62 J. ANTIMICROBIAL CHEMOTHERAPY 83 (2008); M.T.E. Suller & A.D. Russell, *Triclosan and Antibiotic Resistance in Staphylococcus Aureus*, 46 J. ANTIMICROBIAL CHEMOTHERAPY 11 (2000).

325. PFCs appear in household cleaners, shampoos, floor waxes, paints, carpet cleaners, stain removers, car waxes, cosmetics, and other products. NAT'L RISK MGMT. RESEARCH LAB., ENVTL. PROT. AGENCY, PERFLUOROCARBOXYLIC ACID CONTENT IN 116 ARTICLES OF COMMERCE (2009); *PFCs: Global Contaminants*, ENVTL. WORKING GRP. (Apr. 3, 2003), available at <http://www.ewg.org/reports/pfcworld>; *Skin Deep*, supra note 301.

326. See, e.g., Keerthi S. Guruge, *Gene Expression Profiles in Rat Liver Treated with Perfluorooctanoic Acid (PFOA)*, 89 TOXICOLOGICAL SCI. 93, 100, 102 (2006). In January 2005, in a draft assessment, the EPA's Office of Pollution Prevention and Toxics Risk Assessment Division declared PFOA to have some evidence of carcinogenicity, but did not determine that it was at levels sufficient to declare human carcinogenic potential. OFFICE OF POLLUTION PREVENTION & TOXICS RISK ASSESSMENT DIV., ENVTL. PROT. AGENCY, DRAFT PFOA RISK ASSESSMENT OF THE POTENTIAL HUMAN HEALTH EFFECTS ASSOCIATED WITH

thyroid disease,<sup>328</sup> and reproductive toxicity,<sup>329</sup> among other concerns.<sup>330</sup> Public health concerns and EPA investigations have led to a reduction in the use of some of these chemicals.<sup>331</sup>

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EXPOSURE TO PERFLUOROOCTANOIC ACID AND ITS SALTS 84, available at <http://www.epa.gov/oppt/pfoa/pubs/pfoarisk.pdf>. The EPA's Science Advisory Board reviewed those results, and concluded "that the weight-of-evidence conclusion for the potential of PFOA to cause cancer in humans was more aligned and consistent with the hazard descriptor of 'likely to be carcinogenic' as described in the Agency's cancer guidelines (i.e., 2003 EPA Guidelines for Carcinogen Risk Assessment)." SCIENCE ADVISORY BOARD, ENVTL. PROT. AGENCY, SAB REVIEW OF EPA'S DRAFT RISK ASSESSMENT OF POTENTIAL HUMAN HEALTH EFFECTS ASSOCIATED WITH PFOA AND ITS SALTS 2, available at [http://www.epa.gov/sab/pdf/sab\\_06\\_006.pdf](http://www.epa.gov/sab/pdf/sab_06_006.pdf). The EPA has not yet reached a final determination.

327. See, e.g., Camilla Schou Andersen et al., *Prenatal Exposures to Perfluorinated Chemicals and Anthropometric Measures in Infancy*, 172 AM. J. EPIDEMIOLOGY 1230, 1232 (2010); Benjamin J. Apelberg et al., *Cord Serum Concentrations of Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoate (PFOA) in Relation to Weight and Size at Birth*, 115 ENVTL. HEALTH PERSP. 1670, 1674 (2007); Chunyuan Fei et al., *Perfluorinated Chemicals and Fetal Growth: A Study within the Danish National Birth Cohort*, 115 ENVTL. HEALTH PERSP. 1677, 1679 (2007); Noriaki Washino et al., *Correlations Between Prenatal Exposure to Perfluorinated Chemicals and Reduced Fetal Growth*, 117 ENVTL. HEALTH PERSP. 660 (2009).

328. See, e.g., David Melzer et al., *Association Between Serum Perfluorooctanoic Acid (PFOA) and Thyroid Disease in the U.S. National Health and Nutrition Examination Survey*, 118 ENVTL. HEALTH PERSP. 686, 690 (2010).

329. See, e.g., Chunyuan Fei et al., *Maternal Levels of Perfluorinated Chemicals and Subfecundity*, 24 HUM. REPROD. 1200, 1203 (2009).

330. Kellyn S. Betts, *Perfluoroalkyl Acids: What Is the Evidence Telling Us?*, 115 ENVTL. HEALTH PERSP. A250, A255 (2007); Christopher Lau et al., *Perfluoroalkyl Acids: A Review of Monitoring and Toxicological Findings*, 99 TOXICOLOGICAL SCI. 366 (2007); PERFLUORINATED COMPOUNDS (PFCs) AND HUMAN HEALTH CONCERNS, HEALTHY BUILDING NETWORK (2009), available at [http://www.globalhealthandsafety.org/resources/library/2009-04-20PFCs\\_fact\\_sheet.pdf](http://www.globalhealthandsafety.org/resources/library/2009-04-20PFCs_fact_sheet.pdf); CO-OPERATION ON EXISTING CHEMICALS: HAZARD ASSESSMENT OF PERFLUOROOCTANE SULFONATE (PFOS) AND ITS SALTS, ORG. FOR ECON. CO-OPERATION & DEV. (Nov. 21, 2002), available at <http://www.oecd.org/dataoecd/23/18/2382880.pdf>.

331. See Jennifer Lee, *E.P.A. Orders Companies to Examine Effects of Chemicals*, N.Y. TIMES, Apr. 15, 2003, at F2, available at <http://www.nytimes.com/2003/04/15/science/epa-orders-companies-to-examine-effects-of-chemicals.html>. Perfluorooctane Sulfonate ("PFOS") once comprised the principal component of 3M ScotchGuard products, but the company's internal studies and EPA pressure convinced 3M to remove the product from the marketplace. *Id.* Subsequent EPA investigations regarding PFOS and other PFCs that break down into PFOA have led to a stewardship agreement between the EPA and major PFC manufacturers under which the manufacturers commit to a 95% reduction in use of chemicals that break down into PFOA by 2010 and an elimination of use by 2015. 2010/2015 PFOA Stewardship Program, ENVTL. PROT. AGENCY, <http://www.epa.gov/oppt/pfoa/pubs/stewardship/index.html> (last visited Sept. 20, 2011). The EPA also penalized DuPont Chemical \$10.25 million for failure to report under the TSCA the "substantial risk" presented by PFOA. Press Release, Env'tl. Prot. Agency, EPA Settles PFOA Case Against DuPont for Largest Environmental Administrative Penalty in Agency History (Dec. 14, 2005), available at <http://yosemite.epa.gov/opa/admpress.nsf/68b5f2d54f3eefd28525701500517fbf/fdcb2f665cac66bb852570d7005d6665!opendocument>. The EPA has developed an action plan to deal with the risks posed by PFCs. LONG-CHAIN

## 5. Benzene

Benzene functions as a solvent in a wide variety of chemical products.<sup>332</sup> Due to its toxicity, benzene is usually not included as an ingredient in cosmetics and household products; however, research by consumer groups has found it as an impurity in a variety of such products.<sup>333</sup> Benzene is known to the World Health Organization, the U.S. Department of Health and Human Services, the EPA, and the state of California to cause cancer,<sup>334</sup> and is known to cause developmental toxicity in California.<sup>335</sup> Benzene also functions as a neurotoxin<sup>336</sup> and can cause anemia.<sup>337</sup>

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PERFLUORINATED CHEMICALS (PFCs) ACTION PLAN, ENVTL. PROT. AGENCY 17–18 (2009), available at [http://www.epa.gov/opptintr/existingchemicals/pubs/pfcs\\_action\\_plan1230\\_09.pdf](http://www.epa.gov/opptintr/existingchemicals/pubs/pfcs_action_plan1230_09.pdf).

332. Consumers can still encounter benzene as an ingredient in laundry products, lubricating oils, sealants, glues, and furniture waxes. TOXFAQS: BENZENE, AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY, U.S. DEP'T. OF HEALTH AND HUMAN SERVS., 1 (Aug. 2007), available at <http://www.atsdr.cdc.gov/tfacts3.pdf>; *Chemical Profile for Benzene*, SCORECARD: THE POLLUTION INFORMATION SITE, [http://www.scorecard.org/chemical-profiles/summary.tcl?edf\\_substance\\_id=71%2d43%2d2](http://www.scorecard.org/chemical-profiles/summary.tcl?edf_substance_id=71%2d43%2d2) (last visited Sept. 20, 2011).

333. *Skin Deep*, *supra* note 301.

334. *Benzene*, ENVTL. PROT. AGENCY, <http://www.epa.gov/ttn/atw/hlthef/benzene.html> (last visited Sept. 20, 2011); INT'L AGENCY FOR RESEARCH ON CANCER, WORLD HEALTH ORG., 29 IARC MONOGRAPHS ON THE EVALUATION OF CARCINOGENIC RISKS TO HUMANS 93 (1998), available at <http://monographs.iarc.fr/ENG/Monographs/vol29/volume29.pdf>; AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY, U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 332, at 2; STATE OF CALIFORNIA ENVTL. PROTECTION AGENCY, OFFICE OF ENVTL. HEALTH HAZARD ASSESSMENT, CHEMICALS KNOWN TO THE STATE TO CAUSE CANCER OR REPRODUCTIVE TOXICITY (Sept. 2, 2011), available at [http://oehha.ca.gov/prop65/prop65\\_list/files/p65single090211.pdf](http://oehha.ca.gov/prop65/prop65_list/files/p65single090211.pdf).

335. STATE OF CALIFORNIA ENVTL. PROTECTION AGENCY, OFFICE OF ENVTL. HEALTH HAZARD ASSESSMENT, *supra* note 334; see also A.F. Hussein et al., *A Study of Male Reproductive Toxicity in Workers Occupationally Exposed to Benzene*, 5 EUR. UROLOGY SUPPLEMENTS 802 (2006) (studying the effect of Benzene exposure in Egypt).

336. AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY, *supra* note 332; ENVTL. PROT. AGENCY, *supra* note 334.

337. AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY, *supra* note 332; ENVTL. PROT. AGENCY, *supra* note 334.

## 6. Toluene

Toluene, a chemical frequently employed as a theoretically less toxic alternative to benzene,<sup>338</sup> appears in numerous cosmetics and other household products.<sup>339</sup> Toluene is known to the state of California to cause developmental toxicity,<sup>340</sup> and many studies have investigated its function as a neurotoxicant,<sup>341</sup> among other effects.<sup>342</sup> According to the CDC, Toluene is also “the most commonly abused hydrocarbon solvent,”<sup>343</sup> and abuse of it has been linked to fetal solvent syndrome.<sup>344</sup> Compared to other potentially harmful chemicals, such as phthalates and synthetic musks, toluene has been relatively well studied.<sup>345</sup> In 2005 the EPA reviewed a wide range of studies and found extensive evidence of a range of neurological

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338. AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY, U.S. DEP’T OF HEALTH & HUMAN SERVS, CASE STUDIES IN ENVIRONMENTAL MEDICINE: TOLUENE TOXICITY, 8 (Feb. 2001), available at <http://www.atsdr.cdc.gov/csem/toluene/docs/toluene.pdf>.

339. Toluene appears in many household products, including spot removers, paints, car polishes, furniture polishes, glues, household cleaners, moisturizers, nail care products, sealants, and pesticides. *Chemical Profile for Toluene*, SCORECARD: THE POLLUTION INFORMATION SITE, [http://www.scorecard.org/chemical-profiles/summary.tcl?edf\\_substance\\_id=108%2d88%2d3](http://www.scorecard.org/chemical-profiles/summary.tcl?edf_substance_id=108%2d88%2d3) (last visited Sept. 20, 2011); *Skin Deep*, *supra* note 301; DAVID STEINMAN & SAMUEL S. EPSTEIN, *THE SAFE SHOPPER’S BIBLE: A CONSUMER’S GUIDE TO NONTOXIC HOUSEHOLD PRODUCTS, COSMETICS, AND FOOD* 38 (1995).

340. STATE OF CALIFORNIA ENVTL. PROTECTION AGENCY, OFFICE OF ENVTL. HEALTH HAZARD ASSESSMENT, *supra* note 334; see also Scott E. Bowen & John H. Hannigan, *Developmental Toxicity of Prenatal Exposure to Toluene*, 8 AM. ASS’N PHARMACEUTICAL SCIENTISTS J. 419 (2006).

341. Christopher Filley et al., *The Effects of Toluene on the Central Nervous System*, 63 J. NEUROPATHOLOGY & EXPERIMENTAL NEUROLOGY 1 (2004); Vernon A. Benignus et al., *Quantitative Comparisons of the Acute Neurotoxicity of Toluene in Rats and Humans*, 100 TOXICOLOGICAL SCI. 146 (2007); Tin-Tin Win-Shwe & Hidekazu Fujimaki, *Neurotoxicity of Toluene*, 198 TOXICOLOGY LETTERS 93 (2010); ENVTL. PROT. AGENCY, TOXICOLOGICAL REVIEW OF TOLUENE 60–62 (2005), available at <http://www.epa.gov/iris/toxreviews/0118tr.pdf>.

342. SCORECARD, *Toluene*, *supra* note 339; AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY, *supra* note 338; AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY, U.S. DEPT. OF HEALTH & HUMAN SERVS., TOXFAQS: TOLUENE 1–2 (2000), available at <http://www.atsdr.cdc.gov/tfacts56.pdf>.

343. AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY, *supra* note 342, at 1.

344. Fetal solvent syndrome is a condition “in which women who abuse solvents during pregnancy are prone to bearing infants with congenital defects such as developmental delays, microcephaly, and cognitive deficits.” Win-Shwe & Fujimaki, *supra* note 341, at 96; see also Georgianne L. Arnold et al., *Toluene Embryopathy: Clinical Delineation and Developmental Follow-Up*, 93 PEDIATRICS 216 (1994); Bowen & Hannigan, *supra* note 340.

345. ENVTL. PROTECTION AGENCY, *supra* note 341.

effects<sup>346</sup> and some conflicting evidence regarding immunotoxicity,<sup>347</sup> but insufficient evidence to assess its carcinogenic potential.<sup>348</sup>

## 7. Synthetic Musks

Synthetic musks, a group of chemicals used as fragrances,<sup>349</sup> appear in a wide variety of cosmetics and cleaning products.<sup>350</sup> Synthetic musks may cause hormone disruption<sup>351</sup> and increased proliferation of cancer cells,<sup>352</sup> among other possible effects.<sup>353</sup> Studies have also indicated that synthetic musks may weaken the body's resistance to other toxic chemicals, including carcinogens.<sup>354</sup> Toxicity can vary, however, depending on the specific musk included in the product.<sup>355</sup>

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346. *Id.* at 71.

347. *Id.* at 85.

348. *Id.* at 88.

349. SCRANTON, *supra* note 8, at 10.

350. Synthetic musks appear in perfumes, lotions, colognes, body sprays, detergents, cleansers, moisturizers, oils, body creams, body mists, deodorants, shower gels, soaps, shaving creams, shampoos, furniture polishes, fabric softeners, stain removers, cleaners, sanitation wipes, and other products. *Synthetic Musks*, CAMPAIGN FOR SAFE COSMETICS, <http://www.safe-cosmetics.org/article.php?id=643> (last visited Sept. 20, 2011); Jessica L. Reiner & Kurunthachalam Kannan, *A Survey of Polycyclic Musks in Selected Household Commodities from the United States*, 62 CHEMOSPHERE 867, 870–71 (2006); Cornelia Sommer, *The Role of Musk and Musk Compounds in the Fragrance Industry*, in THE HANDBOOK OF ENVIRONMENTAL CHEMISTRY, Vol. 3, Part X 1, 5–15 (Gerhard G. Rimkus ed., 2004); Laurence Roosens et al., *Concentrations of Synthetic Musk Compounds in Personal Care and Sanitation Products and Human Exposure Profiles Through Dermal Application*, 69 CHEMOSPHERE 1540, 1543–45 (2007); PETERS, *supra* note 311.

351. Ninna Toivanen et al., *Effect of Polycyclic Musks on the Aromatase Activity in JEG-3 Chorion Carcinoma Cells*, 180S TOXICOLOGY LETTERS S118 (2008); Richard H.M.M. Schreurs et al., *Interaction of Polycyclic Musks and UV Filters with the Estrogen Receptor (ER), Androgen Receptor (AR), and Progesterone Receptor (PR) in Reporter Gene Bioassays*, 83 TOXICOLOGICAL SCI. 264 (2005); SCRANTON, *supra* note 8, at 10–11.

352. Nikola Bitsch et al., *Estrogenic Activity of Musk Fragrances Detected by the E-Screen Assay Using Human MCF-7 Cells*, 43 ARCHIVES ENVTL. CONTAMINATION & TOXICOLOGY 257 (2002); SCRANTON, *supra* note 8, at 10–11.

353. SARANTIS ET AL., *supra* note 318, at 23–24.

354. Till Luckenbach & David Epel, *Nitromusk and Polycyclic Musk Compounds as Long-Term Inhibitors of Cellular Xenobiotic Defense Systems Mediated by Multidrug Transporters*, 113 ENVTL. HEALTH PERSP. 17 (2005); Heinz H. Schmeiser et al., *Evaluation of Health Risks Caused by Musk Ketone*, 203 INT'L J. HYGIENE & ENVTL. HEALTH 293 (2001); SCRANTON, *supra* note 8, at 10.

355. SCRANTON, *supra* note 8, at 10.

This list provides just a sample of the many ingredients in household chemical products that pose concerns for human health. Some studies also indicate negative health effects from the use of household cleaning products without necessarily referring to specific ingredients; for example, studies have correlated frequent use of household chemical products with respiratory system damage and asthma.<sup>356</sup> Many other component chemicals present significant health issues, but most remain officially unevaluated.<sup>357</sup> Although efforts have been made to decrease the use of some ingredients, such as benzene and formaldehyde, they may also appear as impurities in products even without deliberate inclusion as ingredients.<sup>358</sup> The effects of many of the chemicals in small doses over extended periods of time, as would occur in a home environment, as opposed to high doses for shorter periods, also remains uncertain for many ingredients.<sup>359</sup> The constant use of these chemicals in factories,

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356. Jan-Paul Zock et al., *The Use of Household Cleaning Sprays and Adult Asthma: An International Longitudinal Study*, 176 AM. J. RESPIRATORY & CRITICAL CARE MED. 735 (2007); Andrea Sherriff et al., *Frequent Use of Chemical Household Products is Associated with Persistent Wheezing in Pre-School Age Children*, 60 THORAX 45 (2005); Kenneth D. Rosenman et al., *Cleaning Products and Work-Related Asthma*, 45 J. OCCUPATIONAL & ENVTL. MED. 556 (2003).

357. SCRANTON, *supra* note 8; *see infra* note 473 and accompanying text.

358. Env'tl. Working Grp., Greener School Cleaning Supplies = Fresh Air + Healthier Kids: New Research Links School Air Quality to School Cleaning Supplies 6 (2009), available at <http://www.ewg.org/files/2009/10/school-cleaners/EWGschoolcleaningsupplies.pdf> [hereinafter Env'tl. Working Grp., Greener School Cleaning Supplies] (suggesting that such toxins may result from interactions among products or with the material used to apply the cleaning products); *Skin Deep*, *supra* note 301. Heavy metals, such as arsenic, cadmium, and lead, are of particular concern as impurities in cosmetic products. ENVIRONMENTAL DEFENSE, HEAVY METAL HAZARD: THE HEALTH RISKS OF HIDDEN HEAVY METALS IN FACE MAKEUP 6 (2011), available at [http://environmentaldefence.ca/sites/default/files/report\\_files/HeavyMetalHazard%20FINAL.pdf](http://environmentaldefence.ca/sites/default/files/report_files/HeavyMetalHazard%20FINAL.pdf). A 2011 study of 49 face cosmetic products found arsenic in 20% of tested products, cadmium in 51%, lead in 96%, nickel in 100%, beryllium in 90%, thallium in 61%, and selenium in 14%. HEAVY METAL HAZARD, *supra*, at 4; *see also* Eeva-Liisa Sainio et al., *Metals and Arsenic in Eye Shadows*, 42 CONTACT DERMATITIS 5 (2000) (finding at least one of lead, cobalt, nickel, chromium, and arsenic at a concentration of at least five ppm in 75% of eighty-eight tested eye shadow colors, and at least one of those at a concentration of at least one ppm in all products tested); Nancy M. Hepp et al., *Determination of Total Lead in Lipstick: Development and Validation of a Microwave-Assisted Digestion, Inductively Coupled Plasma–Mass Spectrometric Method*, 60 J. COSM. SCI 405, 413 (2009) (FDA study finding lead in varying concentrations in 100% of lipsticks tested). Heavy metals accumulate in the body, and can cause a variety of serious health problems. HEAVY METAL HAZARD, *supra*, at 18.

359. Duncan, *supra* note 8, at 122–33. For an analysis of potential regulatory approaches to address hazards revealed by scientific research in the field of low-dose toxicity, see Jody A.

salons, and other occupational settings can expose workers in those settings to far greater doses than typical members of the population might receive.<sup>360</sup> Whatever the implications of this scientific research, however, studies have established that humans, including infants, pregnant mothers, and other particularly vulnerable groups,<sup>361</sup> are exposed to a wide range of these chemicals and carry them in their bodies.<sup>362</sup> While some of the data concerning the health effects of

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Roberts, *Collision Course?: Science, Law, and Regulation in the Emerging Science of Low-Dose Toxicity*, 20 VILL. ENVTL. L.J. 1 (2009).

360. See, e.g., Rosenman et al., *supra* note 356; NAT'L HEALTHY NAIL SALON ALLIANCE, *supra* note 300; GORMAN & O'CONNOR, *supra* note 300.

361. See, e.g., JANE HOULIHAN ET AL., BODYBURDEN: THE POLLUTION IN NEWBORNS (2005), available at [http://www.ewg.org/reports\\_content/bodyburden2/pdf/bodyburden2\\_final-r2.pdf](http://www.ewg.org/reports_content/bodyburden2/pdf/bodyburden2_final-r2.pdf); Jennifer J. Adibi et al., *Characterization of Phthalate Exposure Among Pregnant Women Assessed by Repeat Air and Urine Samples*, 116 ENVTL. HEALTH PERSP. 467 (2008); Xibiao Ye et al., *Urinary Metabolite Concentrations of Organophosphorous Pesticides, Bisphenol A, and Phthalates Among Pregnant Women in Rotterdam, the Netherlands: The Generation R Study*, 108 ENVTL. RES. 260 (2008); ERIKA SCHREDER, EARLIEST EXPOSURES: A RESEARCH PROJECT BY WASHINGTON TOXICS COALITION (2009), available at [http://www.watoxics.org/files/EE\\_Report\\_Embargoed\\_WTC.pdf](http://www.watoxics.org/files/EE_Report_Embargoed_WTC.pdf); ENVTL. WORKING GRP., POLLUTION IN PEOPLE: CORD BLOOD CONTAMINANTS IN MINORITY NEWBORNS (2009), available at <http://www.ewg.org/files/2009-Minority-Cord-Blood-Report.pdf>; Manori J. Silva et al., *Detection of Phthalate Metabolites in Human Amniotic Fluid*, 72 BULL. ENVTL. CONTAMINATION & TOXICOLOGY 1226 (2004); Jessica L. Reiner et al., *Synthetic Musk Fragrances in Human Milk from the United States*, 41 ENVTL. SCI. TECH. 3815 (2007); Sheela Sathyanarayana et al., *Baby Care Products: Possible Sources of Infant Phthalate Exposure*, 121 PEDIATRICS e260 (2008); Mary S. Wolff et al., *Pilot Study of Urinary Biomarkers of Phytoestrogens, Phthalates, and Phenols in Girls*, 115 ENVTL. HEALTH PERSP. 116 (2007); Kayoko Kato et al., *Polyfluoroalkyl Compounds in Pooled Sera from Children Participating in the National Health and Nutrition Examination Survey 2001–2002*, 43 ENVTL. SCI. TECH. 2641 (2009).

362. See, e.g., SUTTON, *supra* note 173; CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 173; CATHERINE SCHMITT ET AL., BODY OF EVIDENCE: A STUDY OF POLLUTION IN MAINE PEOPLE (2007), available at <http://www.cleanandhealthyme.org/BodyofEvidence.pdf>; Manori J. Silva et al., *Urinary Levels of Seven Phthalate Metabolites in the U.S. Population from the National Health and Nutrition Examination Survey (NHANES) 1999–2000*, 112 ENVTL. HEALTH PERSP. 331, 337 (2004) (finding phthalate metabolites in 97% of the population tested); Antonia M. Calafat et al., *Polyfluoroalkyl Chemicals in the U.S. Population: Data from the National Health and Nutrition Examination Survey (NHANES) 2003–2004 and Comparisons to NHANES 1999–2000*, 115 ENVTL. HEALTH PERSP. 1596 (2007) (finding PFCs in more than 98% of tested individuals); Hans P. Hutter et al., *Blood Concentrations of Polycyclic Musks in Healthy Young Adults*, 59 CHEMOSPHERE 487, 490 (2005) (finding polycyclic musk compounds in 91% of blood samples from tested young adults); Antonia M. Calafat et al., *Urinary Concentrations of Triclosan in the U.S. Population: 2003–2004*, 116 ENVTL. HEALTH PERSP. 303 (2008) (finding triclosan in 74.6% of urine samples from tested individuals); see also *The Human Toxome Project*, ENVTL. WORKING GRP., <http://www.ewg.org/sites/humantoxome/> (last visited Sept. 20, 2011).

these chemicals remains preliminary or controversial, the lack of testing received by household chemical products and ingredients does not allow for firmer statements.<sup>363</sup>

### *B. Environmental Concerns*

The release of chemicals found in household chemical products can damage the natural environment as well as human health.<sup>364</sup> The chemicals can poison plants and animals, disrupt natural ecosystems, and otherwise negatively impact the environment.<sup>365</sup> The release of the chemicals into aquatic environments through waste water presents particular concerns.<sup>366</sup> In addition, these chemicals may have secondary effects on human health by leaching into sources of drinking water, through consumption of plants and animals that have absorbed the chemicals, through air pollution, and through other means of human exposure.<sup>367</sup>

Just as household chemicals may harm human health, they may also harm the health of plant and animal species. Like *The Jungle* did for public awareness of problems in America's food production, Rachel Carson's *Silent Spring* raised early public awareness of the impact of human chemical use on the natural environment.<sup>368</sup> Since Carson's time, considerable research has been performed on the effects of the release of household chemicals into the environment,

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363. Rawlins, *supra* note 17, at 11–16.

364. FOUND. FOR WATER RESEARCH, HOUSEHOLD CHEMICAL PRODUCTS AND THE WATER ENVIRONMENT 28 (2004), available at <http://www.fwr.org/environw/fr0010.htm>; ERIKA SCHREDER & HEATHER TRIM, WASHINGTON TOXICS COAL., PUGET SOUND DOWN THE DRAIN: HOW EVERYDAY PRODUCTS ARE POLLUTING PUGET SOUND 4–7 (2009), available at [http://watoxics.org/files/PugetSound-DownTheDrain.pdf/at\\_download/file](http://watoxics.org/files/PugetSound-DownTheDrain.pdf/at_download/file).

365. FOUND. FOR WATER RESEARCH, *supra* note 364, at 5; SCHREDER & TRIM, *supra* note 364.

366. FOUND. FOR WATER RESEARCH, *supra* note 364, at 5; SCHREDER & TRIM, *supra* note 364, at 12–15.

367. CENTERS FOR DISEASE CONTROL & PREVENTION, *supra* note 173, at 1.

368. RACHEL CARSON, *SILENT SPRING* (The Riverside Press 1962); MARK H. LYTTLE, *THE GENTLE SUBVERSIVE: RACHEL CARSON, SILENT SPRING, AND THE RISE OF THE ENVIRONMENTAL MOVEMENT* 133–230 (2007). Carson's book revealed the harm, particularly to birds, that is caused when dichlorodiphenyltrichloroethane (DDT), a common pesticide, is released into the environment. *Id.* *Silent Spring* proved to be one of the inspirations for the early environmental movement. *Id.*; JOSEPH V. RODRICKS, *CALCULATED RISKS: THE TOXICITY AND HUMAN HEALTH RISKS OF CHEMICALS IN OUR ENVIRONMENT* 59 (2d ed. 2007).



and the concerns she expressed have not disappeared.<sup>369</sup> Extensive research continues to be performed to determine how the extremely complex interactions between these chemicals and the environment may disrupt natural processes.<sup>370</sup>

Many of the same chemicals that present human health concerns also present environmental concerns, and chemicals that may cause harm to animal species may also harm human health. For example, numerous studies reveal the widespread presence of PFCs in the environment<sup>371</sup> and link them to damage to aquatic organisms and habitats.<sup>372</sup> Other studies have reached similar results concerning the ubiquity<sup>373</sup> and possible environmental harms<sup>374</sup> of synthetic musks.

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369. See, e.g., FOUND. FOR WATER RESEARCH, *supra* note 364; *Toxic Substances Hydrology Program*, U.S. GEOLOGICAL SURVEY, <http://toxics.usgs.gov/index.html> (last visited Sept. 20, 2011).

370. RODRICKS, *supra* note 368, at 318–19.

371. See, e.g., Kristin Inneke Van de Vijver et al., *Perfluorinated Chemicals Infiltrate Ocean Waters: Link between Exposure Levels and Stable Isotope Ratios in Marine Mammals*, 37 ENVTL. SCI. TECH. 5545 (2003); Kurunthachalam Kannan et al., *Perfluorinated Compounds in Aquatic Organisms at Various Trophic Levels in a Great Lakes Food Chain*, 48 ENVTL. CONTAMINATION & TOXICOLOGY 559 (2005); Nobuyoshi Yamashita et al., *A Global Survey of Perfluorinated Acids in Oceans*, 51 MARINE POLLUTION BULL. 658 (2005); M.K. So et al., *Perfluorinated Compounds in the Pearl River and Yangtze River of China*, 68 CHEMOSPHERE 2085 (2007); Mahiba Shoeb et al., *Perfluorinated Chemicals in the Arctic Atmosphere*, 40 ENVTL. SCI. TECH. 7577 (2006); Lau et al., *supra* note 330.

372. See, e.g., Lau et al., *supra* note 330; Betts, *supra* note 330; Kurunthachalam Kannan et al., *Association between Perfluorinated Compounds and Pathological Conditions in Southern Sea Otters*, 40 ENVTL. SCI. TECH. 4943 (2006); Kei Nakayama et al., *Potential Effects of Perfluorinated Compounds in Common Cormorants from Lake Biwa, Japan: An Implication from the Hepatic Gene Expression Profiles by Microarray*, 27 ENVTL. TOXICOLOGY & CHEMISTRY 2378 (2008); Xiongjie Shi et al., *Developmental Toxicity and Alteration of Gene Expression in Zebrafish Embryos Exposed to PFOS*, 230 TOXICOLOGY & APPLIED PHARMACOLOGY 23 (2008); ORG. FOR ECON. CO-OPERATION & DEV., *supra* note 330, at 55–75.

373. See, e.g., Aaron M. Peck & Keri C. Hornbuckle, *Synthetic Musk Fragrances in Urban and Rural Air of Iowa and the Great Lakes*, 40 ATMOSPHERIC ENV'T 6101 (2006); R. Gatermann et al., *Synthetic Musks in the Environment Part 1: Species-Dependent Bioaccumulation of Polycyclic and Nitro Musk Fragrances in Freshwater Fish and Mussels*, 42 ARCHIVES ENVTL. CONTAMINATION & TOXICOLOGY 437 (2001); Haruhiko Nakata, *Occurrence of Synthetic Musk Fragrances in Marine Mammals and Sharks from Japanese Coastal Waters*, 39 ENVTL. SCI. & TECH. 3430 (2005); Kurunthachalam Kannan et al., *Polycyclic Musk Compounds in Higher Trophic Level Aquatic Organisms and Humans from the United States*, 61 CHEMOSPHERE 693 (2005); Heinz Rudel et al., *Retrospective Monitoring of Synthetic Musk Compounds in Aquatic Biota from German Rivers and Coastal Areas*, 18 J. ENVTL. MONITORING 812 (2006); Aaron M. Peck et al., *Synthetic Musk Fragrances in Lake Erie and Lake Ontario Sediment Cores*, 40 ENVTL. SCI. TECH. 5629 (2006).

Some studies have also found phthalates in significant quantities in aquatic environments<sup>375</sup>—quantities that may be toxic to a wide range of organisms.<sup>376</sup> In addition, some studies have associated the ubiquitous use of triclosan<sup>377</sup> with possible environmental harm,<sup>378</sup> particularly through wastewater pollution. These and many other

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374. See, e.g., Luckenbach et al., *supra* note 354; Daniel R. Dietrich & Bettina C. Hitzfeld, *Bioaccumulation and Ecotoxicity of Synthetic Musks in the Aquatic Environment* 3 THE HANDBOOK OF ENVTL. CHEMISTRY 233 (2004); Leah Wollenberger et al., *Inhibition of Larval Development of the Marine Copepod *Arctia tonsa* by Four Synthetic Musk Substances*, 305 SCI. TOTAL ENV'T 53 (2003); Hubertus Brunn et al., *Toxicology of Synthetic Musk Compounds in Man and Animals*, HANDBOOK ENVTL. CHEMISTRY 259 (2004); Sabine Schnell et al., *The Interference of Nitro- and Polycyclic Musks with Endogenous and Xenobiotic Metabolizing Enzymes in Carp: An In Vitro Study*, 43 ENVTL. SCI. TECH. 9458 (2009); M.P. Gooding et al., *Toxicity of Synthetic Musks to Early Life Stages of the Freshwater Mussel *Lampsilis cardium**, 51 ARCHIVES CONTAMINATION & TOXICOLOGY 549 (2006).

375. Hermann Fromme et al., *Occurrence of Phthalates and Bisphenol A and F in the Environment*, 36 WATER RES. 1429 (2002); S.Y. Yuan et al., *Occurrence and Microbial Degradation of Phthalate Esters in Taiwan River Sediments*, 49 CHEMOSPHERE 1295 (2002).

376. See, e.g., Hung-Hung Sung et al., *Effects and Toxicity of Phthalate Esters to Hemocytes of Giant Freshwater Prawn, *Macrobrachium rosenbergii**, 64 AQUATIC TOXICOLOGY 25 (2003); Ying Liu et al., *Toxicity of Seven Phthalate Esters to Embryonic Development of the Abalone *Haliotis diversicolor supertexta**, 18 ECOTOXICOLOGY 293 (2009); Nivedita Ghorpade et al., *Toxicity Study of Diethyl Phthalate on Freshwater Fish *Cirrhina mrigala**, 53 ECOTOXICOLOGY & ENVTL. SAFETY 255 (2002).

377. See, e.g., Talia E. A. Chalew & Rolf U. Halden, *Environmental Exposure of Aquatic and Terrestrial Biota to Triclosan and Triclocarban*, 45 J. AM. WATER RESOURCES ASS'N 4 (2009); Anton Lindstrom et al., *Occurrence and Environmental Behavior of the Bactericide Triclosan and Its Methyl Derivative in Surface Waters and in Wastewater*, 36 ENVTL. SCI. TECH. 2322 (2002); Heinz Singer et al., *Triclosan: Occurrence and Fate of a Widely Used Biocide in the Aquatic Environment: Field Measurements in Wastewater Treatment Plants, Surface Waters, and Lake Sediments*, 36 ENVTL. SCI. TECH. 4998 (2002); Dana W. Kolpin et al., *Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999–2000: A National Reconnaissance*, 36 ENVTL. SCI. TECH. 1202, 1202 (2002); LISE SAMSØE-PETERSEN ET AL., DANISH ENVTL. PROT. AGENCY, FATE AND EFFECTS OF TRICLOSAN (2003), available at <http://www2.mst.dk/udgiv/publications/2003/87-7972-984-3/pdf/87-7972-985-1.pdf>.

378. See, e.g., Marinella Farré et al., *Assessment of the Acute Toxicity of Triclosan and Methyl Triclosan in Wastewater Based on the Bioluminescence Inhibition of *Vibrio fischeri**, 390 ANALYTICAL & BIOANALYTICAL CHEMISTRY 1999 (2008); Norihisa Tatarazako et al., *Effects of Triclosan on Various Aquatic Organisms*, 11 ENVTL. SCI. 133 (2004); Rhaul Oliveira et al., *Effects of Triclosan on Zebrafish Early-Life Stages and Adults*, 16 ENVTL. SCI. & POLLUTION RES. 679 (2009); David R. Orvos et al., *Aquatic Toxicity of Triclosan*, 21 ENVTL. TOXICOLOGY & CHEMISTRY 1338 (2002); Hiroshi Ishibashi et al., *Effects of Triclosan on the Early Life Stages and Reproduction of Medaka *Oryzias latipes* and Induction of Hepatic Vitellogenin*, 67 AQUATIC TOXICOLOGY 167 (2004); Claudia Cimiglia et al., *Application of Methods for Assessing the Geno- and Cytotoxicity of Triclosan to *C. ehrenbergii**, 122 J. HAZARDOUS MATERIALS 227 (2005); SAMSØE-PETERSEN ET AL., *supra* note 377; Veldhoen et al., *supra* note 321.

household chemical ingredients pose substantial risks of environmental harm, although the degree and extent of these risks are, in many cases, ambiguous.

As with the health effects, many of the environmental consequences remain unclear and the supporting data preliminary. Although the evidence for some health and environmental effects is clearer than for others, the enduring theme is uncertainty, with definitive data largely absent.<sup>379</sup> In addition to the health and environmental effects directly caused by the chemicals, much uncertainty exists regarding the potential consequences of the combinations that the chemicals may form with each other in the home and the broader environment.<sup>380</sup> Some chemicals may break down in the environment and the human body, while others tend to accumulate over time.<sup>381</sup> Given this uncertainty and the nature of the scientific process, regulators cannot achieve a zero-risk standard, and they must balance public and environmental safety concerns against economic costs, at least to some extent.<sup>382</sup> While this uncertainty may not permit outright bans based on the slightest uncertainty,<sup>383</sup> a wide range of regulatory discretion remains available, and labeling serves as a solution where uncertainty does not allow for a ban.<sup>384</sup>

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379. See Richard M. Sharpe & D. Stewart Irvine, *How Strong Is the Evidence of a Link Between Environmental Chemicals and Adverse Effects on Human Reproductive Health?*, 328 BRIT. MED. J. 447, 447 (2004); RODRICKS, *supra* note 368, at 209–13.

380. See WILLIAM W. NAZAROFF ET AL., CAL. AIR RES. BD., INDOOR AIR CHEMISTRY: CLEANING AGENTS, OZONE AND TOXIC AIR CONTAMINANTS 133 (2006), available at [http://www.arb.ca.gov/research/apr/past/01-336\\_a.pdf](http://www.arb.ca.gov/research/apr/past/01-336_a.pdf); Duncan, *supra* note 8, at 133; Kolpin et al., *supra* note 377, at 1210.

381. Synthetic musks, for example, have been shown to bioaccumulate in human and animal tissues and in the broader environment. See, e.g., Dietrich & Hitzfeld, *supra* note 374; Gatermann et al., *supra* note 373; Kannan et al., *supra* note 373; Reiner et al., *supra* note 373; Hutter et al., *supra* note 362.

382. RODRICKS, *supra* note 368, at 284–90.

383. Sharpe, *supra* note 379, at 447; RODRICKS, *supra* note 368, at 284–90 (“It should be clear by now that risk assessors do not know how to draw a sharp line between ‘safe’ and ‘unsafe’ exposures to any chemical. The very notion of ‘safety’ is scientifically wrongheaded, if by it is meant the absolute absence of risk.”). Of course, regulators should set any safety standards at a level that, within reason and within the limits of scientific understanding, minimizes risk or chooses the most ecologically sound alternative, and this level may still result in the ban of many chemicals. See *infra* note 482 and accompanying text; Rawlins, *supra* note 17, at 46–50.

384. For an analysis of environmental chemicals from a risk assessment and management perspective, and discussing the difficulties presented by inadequate information and the

## V. ANALYSIS

Researchers have generally considered the current nutritional labeling scheme administered by the FDA a success.<sup>385</sup> Numerous

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complex nature of scientific research in this area, see RODRICKS, *supra* note 368. Some environmentalists have argued against the use of risk assessment, at least as it is currently formulated, in environmental decision-making. See, e.g., MARY O'BRIEN, MAKING BETTER ENVIRONMENTAL DECISIONS: AN ALTERNATIVE TO RISK ASSESSMENT (2000) (promoting "alternatives assessment" as a more ecologically sound replacement for risk assessment); Robert R. Kuehn, *The Environmental Justice Implications of Quantitative Risk Assessment*, 1996 U. ILL. L. REV. 103; Ellen K. Silbergeld, *Risk Assessment: The Perspective and Experience of U.S. Environmentalists*, 101 ENVTL. HEALTH PERSP. 100 (1993). Whatever the method of regulation used (or decided-upon), "society cannot feasibly eliminate all carcinogenic risks nor enjoin use of all toxic substances. Society must therefore develop some rational method for deciding which risks are unacceptable and for allocating scarce regulatory resources." Howard Latin, *Good Science, Bad Regulation, and Toxic Risk Assessment*, 5 YALE J. ON REG. 89, 147 (1988). However, risk assessment need not be confined to purely economic considerations. See *id.* at 148 (arguing that because "predictions of toxic effects generally cannot be grounded on reliable scientific judgments, social policy criteria must play an influential role in the choice among competing risk estimates").

385. See, e.g., Brenda M. Derby & Alan S. Levy, *Do Food Labels Work?: Gauging the Effectiveness of Food Labels Pre- and Post-NLEA*, in HANDBOOK OF MARKETING AND SOCIETY 372, 372–98 (Paul N. Bloom & Gregory T. Gundlach eds., 2001) (reviewing studies concerning consumer use of food labels and concluding that labels positively influenced purchasing decisions); Alan D. Mathios, *The Impact of Mandatory Disclosure Laws on Product Choices: An Analysis of the Salad Dressing Market*, 43 J. L. & ECON. 651 (2000) (concluding that the move to mandatory labeling under the NLEA resulted in lower sales for higher-fat salad dressings); Jayachandran N. Variyam & John Cawley, *Nutrition Labels and Obesity*, (Nat'l Bureau of Econ. Res., Working Paper No. W11956 2006) (concluding that following the passage of the NLEA obesity rates declined among consumers who used nutrition labels as opposed to those who did not); Marian L. Neuhouser et al., *Use of Food Nutrition Labels is Associated with Lower Fat Intake*, 99 J. AM. DIETETIC ASS'N 45, 49–50 (1999) (concluding that use of post-NLEA nutrition labeling by consumers reduced their fat consumption); Alan R. Kristal et al., *Trends in Food Labeling Use Associated with New Nutrition Labeling Regulations*, 88 AM. J. PUB. HEALTH 1212, 1214–15 (1998) (concluding that the NLEA and related FDA labeling rules increased use of nutrition labels by consumers); Jessie A. Satia et al., *Food Nutrition Label Use Is Associated with Demographic, Behavioral, and Psychosocial Factors and Dietary Intake Among African Americans in North Carolina*, 105 J. AM. DIETETIC ASS'N 392, 399–401 (2005) (concluding that nutrition label use increased fruit and vegetable consumption and reduced fat intake among African Americans in North Carolina); Sung-Yong Kim et al., *The Effect of Food Label Use on Nutrient Intakes: An Endogenous Switching Regression Analysis*, 25 J. AGRIC. & RESOURCE ECON. 215 (2000) (finding that label use improved appropriate consumption of fiber and decreased the intake of calories from total fat, saturated fat, cholesterol, and sodium); Robert E. Post et al., *Use of the Nutrition Facts Label in Chronic Disease Management: Results from the National Health and Nutrition Examination Survey*, 110 J. AM. DIETETIC ASS'N 628 (2010) (finding that patients with chronic disease who read food labels consumed less calories, saturated fat, carbohydrates, and sugar, and more fiber); D. Weaver & M. Finke, *The Relationship Between the Use of Sugar Content Information*

studies have found that consumers read nutrition labels, that the labels influence their purchasing decisions, and that those decisions ultimately improve the health of those consumers.<sup>386</sup> The labeling scheme has positively influenced patterns of nutrient intake; fat, cholesterol, and sodium consumption; and other nutritional factors.<sup>387</sup> Since the development of the modern food label following the passage of the NLEA, the label's consistent and ubiquitous presence on food products has broadened consumers' awareness of nutritional factors affecting their health,<sup>388</sup> encouraged discussion of nutrition issues in public discourse, and led to a more active role for food manufacturers as nutrition information providers.<sup>389</sup> The success of

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*on Nutrition Labels and the Consumption of Added Sugars*, 28 FOOD POL'Y 213, 217–19 (2003) (finding that frequent use of labels for information regarding sugar content was associated with lower added sugar consumption).

386. However, the success of the nutrition labeling program does not mean that American food consumption is flawless. Indeed, by some measures, the nutritional quality of the average American diet has deteriorated in recent decades. And as a result, obesity rates have increased noticeably since 1985. *U.S. Obesity Trends*, CTR. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/obesity/data/trends.html> (last visited Sept. 20, 2011). Studies indicate that the prevalence of certain ingredients like high fructose corn syrup have contributed to the development of chronic diseases such as diabetes. *See, e.g.*, Lee S. Gross et al., *Increased Consumption of Refined Carbohydrates and the Epidemic of Type 2 Diabetes in the United States: An Ecologic Assessment*, 79 AM. J. CLINICAL NUTRITION 774, 776–78 (2004). Critics of American eating patterns have pointed to increased consumption of processed foods and the lack of unrefined foods such as fresh fruits and vegetables typical of the American diet. *See, e.g.*, MICHAEL POLLAN, *THE OMNIVORE'S DILEMMA: A NATURAL HISTORY OF FOUR MEALS* (2006). However, these criticisms do not provide an argument against nutrition and ingredient labeling. As the previously cited studies reveal, the labels effectively improve the food consumption patterns of those who use them. *See supra* note 385. And food labeling is just one weapon in the arsenal available to improve American eating habits. Indeed, consumers could not act on information concerning, say, the possible negative health effects of high fructose corn syrup consumption without knowing which foods contained the syrup. Nutrition labeling provides a source of information that can, and does, educate consumers and provide a starting point for discussion of nutrition issues in society. *See supra* note 385. Chemical labeling would serve the same purposes.

387. *See supra* note 385. The nutrition labeling scheme has also resulted in changes in the products released into the marketplace by food producers. Bruce A. Silverglade, *The Nutrition Labeling and Education Act—Progress to Date and Challenges for the Future*, 15 J. PUB. POL'Y & MARKETING 148, 148 (1996). Manufacturers have replaced foods high in ingredients such as fat and sugar with healthier ones. Nicole Fradette et al., *The Impact of the Nutrition Labeling and Education Act of 1990 on the Food Industry*, 47 ADMIN. L. REV. 605, 616–17 (1995). This means that “consumers who may not even read the nutrition label will still benefit as manufacturers reformulate products.” Silverglade, *supra*.

388. *See supra* note 385.

389. Fradette et al., *supra* note 387, at 618.

the labeling laws has resulted in calls for their expansion to cover foods served in restaurants and other locations,<sup>390</sup> labeling on supermarket shelves and the front of packages,<sup>391</sup> and for the inclusion of even broader categories of information, such as whether the products contain genetically modified ingredients.<sup>392</sup>

Despite the broadly positive reception the nutritional labeling scheme has received, some commentators have pointed out defects in its design.<sup>393</sup> Some note the scheme's failure to make labeling accessible to specific groups such as children,<sup>394</sup> the elderly,<sup>395</sup> and the poor.<sup>396</sup> Others criticize the FDA's willingness to permit food

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390. See, e.g., Scot Burton & Elizabeth Creyer, *What Consumers Don't Know Can Hurt Them: Consumer Evaluations and Disease Risk Perceptions of Restaurant Menu Items*, 38 J. CONSUMER AFFAIRS 121 (2005); Rebecca S. Fribush, *Putting Calorie and Fat Counts on the Table: Should Mandatory Nutritional Disclosure Laws Apply to Restaurant Foods?*, 73 GEO. WASH. L. REV. 377 (2005).

391. See, e.g., Jason E. Lang et al., *Use of a Supermarket Shelf-Labeling Program to Educate a Predominately Minority Community About Foods that Promote Heart Health*, 100 J. AM. DIETETIC ASS'N 804, 808–09 (2000); Annette Maggi, *Regulatory Update: Front-of-Package Icons and Shelf Labeling Programs*, 6 OBESITY & WEIGHT MGMT. 77, 77 (2010).

392. See, e.g., Beaudoin, *supra* note 125, at 278; Marion Nestle, *Food Biotechnology: Labeling Will Benefit Industry As Well As Consumers*, 33 NUTRITION TODAY 6 (1998).

393. Some critics have argued that some aspects of mandatory labeling violate manufacturers' First Amendment rights. See, e.g., Lars Noah, *The Little Agency that Could (Act with Indifference to Constitutional and Statutory Strictures)*, 93 CORNELL L. REV. 901 (2008); Steven B. Steinborn & Kyra A. Todd, *The End to Paternalism: A New Approach to Food Labeling*, 54 FOOD & DRUG L.J. 401 (1999). This proposition has some case law support. See, e.g., *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) (striking down certain FDA restrictions on health claims in dietary supplement labeling); *Whitaker v. Thompson*, 248 F. Supp. 2d 1 (D.D.C. 2002) (deciding that the FDA must allow certain health claims on dietary supplement labeling); *Alliance for Natural Health U.S. v. Sebelius*, 714 F. Supp. 2d 48 (D.D.C. 2010) (same); *Alliance for Natural Health U.S. v. Sebelius*, 786 F. Supp. 2d 1 (D.D.C. 2011) (same). However, these issues are beyond the scope of this Note.

394. See, e.g., Javitt, *supra* note 122, at 360–61; Sabrina M. Neeley & Brianne Petricone, *Children's (Mis)understanding of Nutritional Information on Product Packages: Seeking Ways to Help Kids Make Healthier Food Choices*, 33 ADVANCES CONSUMER RES. 556, 556–57 (2006).

395. See, e.g., Janet F. Macon et al., *Food Label Use by Older Americans: Data From the Continuing Survey of Food Intakes by Individuals and the Diet and Health Knowledge Survey*, 24 J. NUTRITION FOR THE ELDERLY 35 (2004); Carol Byrd-Bredbenner & Laurie Kiefer, *The Ability of Elderly Women to Perform Nutrition Facts Label Tasks and Judge Nutrient Content Claims*, 20 J. NUTRITION FOR THE ELDERLY 29 (2000); Scot Burton & J. Craig Andrews, *Age, Product Nutrition, and Label Format Effects on Consumer Perceptions and Product Evaluations*, 30 J. CONSUMER AFF. 68 (1996).

396. See, e.g., Laura McArthur et al., *Behaviors, Attitudes, and Knowledge of Low-Income Consumers Regarding Nutrition Labels*, 12 J. HEALTH CARE FOR POOR & UNDERSERVED 415, 425–27 (2001).

manufacturers to make various health claims<sup>397</sup> and to apply their own labeling designs.<sup>398</sup> Still others push for labeling of genetically modified foods and other categories of products.<sup>399</sup> Although the FDA and Congress must balance these concerns against the need to maintain a clear and uniform labeling system, and must ensure that the burden of compliance on food product manufacturers does not overwhelm them, future regulations may address these complaints.

Both the successes and failures of the modern nutritional labeling scheme have implications for the design of a future household chemical labeling scheme. While the first and perhaps most basic lesson may be that an industry-wide ingredient labeling scheme can successfully achieve the information and behavior modification goals set for it,<sup>400</sup> other lessons deserve discussion. This Note divides these lessons into issues of breadth—ensuring that future labeling schemes address enough issues and identify enough components to properly inform consumers; accessibility—ensuring that as many consumers as possible benefit from labeling; uniformity—preventing confusion and improving regulatory efficiency by ensuring consistent labeling; clarity—ensuring that consumers find labeling clear and easy to understand; education—ensuring that consumers understand the relationship between the chemical ingredients and their health; and testing, standards, and enforcement—ensuring that the representations on the labels match the contents of the packages and that all components meet the appropriate safety standards. The essence of the proposed labeling program, however, is consumer choice<sup>401</sup>—the principle that consumers should have the power to

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397. See, e.g., Clare M. Hasler, *Health Claims in the United States: An Aid to the Public or a Source of Confusion?*, 138 J. NUTRITION 1216S, 1218S–9S (2008).

398. See, e.g., Marion Nestle & David S. Ludwig, *Front-of-Package Food Labels: Public Health or Propaganda?*, 303 J. AM. MED. ASS'N 771, 771 (2010).

399. See *supra* note 125 and associated text.

400. See *supra* note 385 and associated text.

401. Consumer choice theory is a theory based in microeconomics. See, e.g., GORDON FOXALL, *UNDERSTANDING CONSUMER CHOICE* (2005); JAMES R. BETTMAN, *INFORMATION PROCESSING THEORY OF CONSUMER CHOICE* (1979). This economic theory, and its broader philosophical underpinnings, are largely beyond the scope of this Note. For an application of consumer choice theory to nutritional labeling in the context of fast food products, see McCann, *supra* note 124.

decide the chemicals to which they are willing to expose themselves and their environment.

#### A. Breadth

The failure to disclose sufficient information concerning household chemical products so as to permit consumers to make informed purchasing decisions represents the most basic and damaging flaw in the current labeling system.<sup>402</sup> The FHSA, and the regulations issued pursuant to it, do require labeling of a household chemical ingredient if it meets the definition of a “hazardous substance.”<sup>403</sup> However, the regulations do not permit issuance of a warning unless “sufficient”<sup>404</sup> or “limited”<sup>405</sup> evidence of its toxic effect on humans or animals, or “limited” evidence of its toxic effect on humans, exists.<sup>406</sup> But this requirement ignores the reality of scientific testing. Unless the scientific community already considers a chemical almost indisputably safe, it will not perform tests using that substance on human subjects.<sup>407</sup> Without human tests,<sup>408</sup> meeting the

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402. Sarah C. Dunagan et al., *Toxics Use Reduction in the Home: Lessons Learned from Household Exposure Studies*, 19 J. CLEANER PRODUCTION 438, 441–42 (2011).

403. 15 U.S.C. § 1261(f) (2006).

404. The definition of “sufficient” evidence from animal studies varies somewhat depending on whether the risk involves carcinogenicity, neurotoxicity, or other hazards. However, it generally requires that experiments “elicit a statistically significant ( $p < 0.05$ ) treatment-related increase in multiple endpoints in a single species/strain, or in the incidence of a single endpoint at multiple dose levels or with multiple routes of administration in a single species/strain, or increase in the incidence of a single endpoint in multiple species/strains/experiments.” 16 C.F.R. § 1500.135(c)(1)(iii)(B) (2009). For human studies, “sufficient” evidence generally requires that “[n]o identified bias that can account for the observed association has been found,” that “[a]ll possible confounding factors which could account for the observed association can be ruled out with reasonable confidence,” and that “[b]ased on statistical analysis, the association has been shown unlikely to be due to chance.” *Id.* § 1500.135(c)(1)(i).

405. The definition of “limited” evidence from human studies also varies somewhat depending on whether the risk involves carcinogenicity, neurotoxicity, or other hazards, but generally it requires that a “causal interpretation is credible, but chance, bias, or other confounding factors could not be ruled out with reasonable confidence.” *Id.* § 1500.135(a)(2)(i). Except for substances presenting a risk of reproductive toxicity, “limited” evidence from animal studies results in a determination that the substance is “not considered ‘toxic.’” *Id.* § 1500.135(a)(3).

406. 16 C.F.R. § 1500.135(a)-(c) (2009).

407. Indeed, the “Common Rule” employed by the federal government to approve human subject research generally requires both informed consent and that the risks to the subjects are



standard requires very convincing evidence from animal tests, a difficult standard to meet.<sup>409</sup> Even if the CPSC acquired the evidence, it would still have to prove that the substance meets the FHSA's definition of "toxic" and that humans have the potential to be exposed to it.<sup>410</sup> Given the extensive scientific uncertainty, without full labeling of all ingredients even adequate labeling of toxic chemicals according to CPSC definitions would deprive consumers of the opportunity and ability to make informed choices regarding the chemicals they buy.<sup>411</sup> Even when evidence of toxicity seems almost certain, the limitations on the CPSC's powers under the CPSA, the FHSA, and its own regulations have resulted in a failure to act.<sup>412</sup> The FDA, under the FD&C Act, has greater power to order cosmetic labeling, and has exercised that power to require some limited ingredient labeling.<sup>413</sup> However, exceptions such as those permitting manufacturers the ability to claim trade secret protection and the power to label fragrances with just the term "fragrance," rather than with the name of the chemical, has significantly restricted the scope of ingredient labeling.<sup>414</sup> In addition, the FDA's failure to mandate testing prior to sale has rendered the cosmetics labeling requirements

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"reasonable in relation to anticipated benefits, if any, to [the] subjects, and [to] the importance of the knowledge that may reasonably be expected to result." 45 C.F.R. § 46.111 (2009). The benefits would not include benefits that the subject "would receive even if not participating in the research," or "possible long-range effects of applying knowledge gained in the research." *Id.* Scientists would struggle to obtain human subjects or the permission necessary to test potentially risky chemical ingredients on them under those guidelines.

408. While studies of populations that are exposed to a substance can provide some evidence for a substance's toxicity in humans, ruling out "[a]ll possible confounding factors," as the regulation requires, presents a difficult standard. 16 C.F.R. § 1500.135(c)(1)(C) (2009).

409. See 16 C.F.R. § 1500.135(c)(1)(iii)(B) (2009).

410. 15 U.S.C. § 1261(g) (2006); 16 C.F.R. § 1500.135(d).

411. See *supra* notes 379–84 and accompanying text; Sharpe, *supra* note 379, at 447; RODRICKS, *supra* note 368, at 284–90.

412. For example, the CPSC had evidence of formaldehyde's hazard as a carcinogen at least as early as 1981, while the EPA had evidence at least as early as 1987. See NAT'L INST. FOR OCCUPATIONAL SAFETY & HEALTH, *supra* note 302; OFFICE OF AIR AND RADIATION, ENVTL. PROTECTION AGENCY, *supra* note 302. Despite mounting evidence to the point that the World Health Organization branded it a "known carcinogen," the CPSC has failed to ensure that products that emit formaldehyde when used bear appropriate labeling. INT'L AGENCY FOR RES. ON CANCER, *supra* note 303; ENVTL. WORKING GRP., GREENER SCHOOL CLEANING SUPPLIES, *supra* note 358.

413. See FOOD AND DRUG ADMIN., *supra* note 174.

414. Gervin, *supra* note 177, at 327–29. The SCA of 2011 would rescind these exemptions. H.R. 2359 § 613(a); H.R. 2359 § 611(4)(A); H.R. 2359 § 613(f).

ineffectual since the accuracy of the labels and the health concerns of the chemicals on them remain uncertain.<sup>415</sup> The evidence that household chemical products may release potentially hazardous chemicals via impurities rather than from intentionally added ingredients<sup>416</sup> calls for the labeling of products that could release those impurities. Nor do the current labeling regulations account for chemicals that consumers may wish to avoid because of their harmful effects on the natural environment.<sup>417</sup> Thus, adequate household chemical labeling requires disclosure of all components, not just those currently considered toxic, and the labeling of all household chemical products, not just those already recognized as hazardous.

The current state of household chemical labeling is grossly inadequate to meet the informational needs of consumers. Insufficient statutes, bureaucratic failures, and an industry unwilling or unable to adequately police itself have left consumers exposed to a vast range of actual and potential toxins.<sup>418</sup> Similarly, when nutritional labeling commenced in 1906 it required little more than that any statements made on the packaging be accurate,<sup>419</sup> and insufficient and misleading labeling abounded.<sup>420</sup> However, beginning in 1913 with the Gould Amendment and reaching full ingredient and nutrient disclosure with the passage of the NLEA, nutritional labeling has gradually reached the present state of mandatory labeling of all product components.<sup>421</sup> Congress can learn from this experience. New regulations can dispense with this slow and stumbling approach by requiring labeling of all ingredients along with appropriate cautionary statements.<sup>422</sup> Such labeling would permit consumers to understand, at the time of purchase, what risks they assume by using the products they buy.

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415. Rawlins, *supra* note 17, at 11–13.

416. ENVTL. WORKING GRP., GREENER SCHOOL CLEANING SUPPLIES, *supra* note 358.

417. See *supra* notes 364–78 and accompanying text.

418. Wilson & Schwarzman, *supra* note 19, at 1204–5; Rawlins, *supra* note 17, at 1–35.

419. Pure Food and Drug Act of 1906, Pub. L. No. 59-384, § 8, 34 Stat. 768 (1906).

420. Janssen, *supra* note 35, at 428.

421. Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, § 2, 104 Stat. 2353 (1990) (codified as amended at 21 U.S.C. § 343).

422. Dunagan et al., *supra* note 402, at 441–42.

Admittedly, the issues presented by potential household chemical labeling do not completely track those involved in nutritional labeling. Manufacturers of chemical products do have legitimate concerns regarding the protection of their intellectual property in the formulation of their products.<sup>423</sup> However, even if the household chemical manufacturers' need to protect trade secrets was greater than the food manufacturers' need to protect their secrets (an assertion far from proven),<sup>424</sup> manufacturers' rights and any potential value to the public from those trade secrets<sup>425</sup> must be balanced against the harm to consumers from the hidden risks that they may be assuming when they use those household chemical products.<sup>426</sup> Indeed, far from suppressing innovation in the design of new food products, full disclosure in food labeling has been credited with encouraging manufacturers to create healthier products, a clear benefit to consumers.<sup>427</sup> Even if the new regulations impose significant costs on the chemical industry, those costs must be weighed against the monetary and health benefits to society of

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423. Wayne, *supra* note 275; *see also* Gervin, *supra* note 177, at 334.

424. Experience with nutrition labeling suggests that the disclosure of ingredients would not necessarily stifle the development of new products, which is one of the main traditional arguments for maintenance of trade secrets. *See, e.g.*, CHRISTOPHER M. KALANJE, WORLD INTEL. PROP. ORG., *ROLE OF INTELLECTUAL PROPERTY IN INNOVATION AND NEW PRODUCT DEVELOPMENT* (2005), available at [http://www.wipo.int/export/sites/www/sme/en/documents/pdf/ip\\_innovation\\_development.pdf](http://www.wipo.int/export/sites/www/sme/en/documents/pdf/ip_innovation_development.pdf). Since the passage of the NLEA, the food industry has seen a dramatic increase in functional foods, products made from soy, olestra, and other cutting edge ingredients, and other new food products that have required extensive research and development. The requirement that the ingredients appear on food labels does not appear to have halted innovation in the food industry, and in fact it has refocused some of that innovation into the development of healthier products. *See supra* note 387.

425. *See* Gervin, *supra* note 177, at 338–40 (arguing that dispensing with trade secret protection for cosmetics ingredients would not significantly breach the principles of trade secret law).

426. *See supra* Part IV.

427. *See supra* note 387. Admittedly, this has not been without its costs; an FDA estimate prior to the implementation of the NLEA placed its cost at \$1.3 billion to food manufacturers. Regulatory Impact Analysis of the Proposed Rules to Amend the Food Labeling Regulations, 56 Fed. Reg. 60,856, 60,857 (Nov. 27, 1991). However, the same document estimated that the NLEA would save “80,900 life-years,” and achieve benefits of up to \$21 billion based on those life-years saved. *Id.* (“The monetary value of the benefits [number of life-years saved] of this regulation is estimated to be \$3.6 billion [discounted at 5 percent over a 20-year period]. Valuing benefits based on the number of lives saved would raise this value to \$21 billion [discounted at 5 percent over a 20-year period]”). However, these comparisons of the value of dollars to increased life spans are difficult to quantify or justify.

decreased rates of cancer, birth defects, and other health savings, as well as potential benefits to the natural environment.<sup>428</sup> Such benefits are, of course, highly speculative and difficult to measure; however, the potential costs to industry cannot be considered in isolation (and are, of course, also speculative and uncertain).<sup>429</sup> To placate some of the chemical industry's fears, labeling could include just the names of the chemicals, whether their amount passes certain threshold values, and appropriate cautionary statements, rather than disclosure of the precise quantities or percentages, thus preventing the release of exact formulations.

### *B. Accessibility*

Much discussion regarding the labeling of both food and chemical products centers around the need to inform children.<sup>430</sup> But the modern food label, relying on percentages of daily values, serving sizes, and quantities of various nutrients, can confuse or mislead younger consumers.<sup>431</sup> Similar risks exist with a potential chemical labeling scheme.<sup>432</sup> Given the high rate of child poisonings in the United States,<sup>433</sup> the obvious knowledge gaps between children and

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428. At the time of passage of the NLEA, the FDA made estimates concerning similar impacts on the food industry and on society as a whole. *See* Regulatory Impact Analysis of the Proposed Rules to Amend the Food Labeling Regulations, 56 Fed. Reg., *supra* note 427, at 60,857. No similar estimates by nonpartisan entities seem to have been made for the potential impacts on the chemical industry or society of the passage of regulations requiring household chemical ingredient labeling.

429. This Note will not attempt a complete analysis of the intellectual property ramifications of a household chemical labeling scheme. For a detailed argument in favor of mandatory labeling of cosmetics and against an interpretation of the takings clause of the Fifth Amendment that would deny the government the power to require such labeling, see Gervin, *supra* note 177.

430. *See, e.g.*, Kid-Safe Chemicals Act, H.R. 6100, 110th Cong. § 502 (2008); Kid-Safe Chemicals Act, S. 3040, 110th Cong. § 502 (2008); Javitt, *supra* note 122, at 360–61.

431. Javitt, *supra* note 122, at 327–29.

432. Recent household chemical regulation legislation, such as the Kid-Safe Chemicals Act and the CPSIA, has included provisions that address the need to protect children. *See, e.g.*, H.R. 6100 § 502; S. 3040 § 502; Consumer Product Safety Improvement Act, Pub. L. No. 110-314 tit. 1, 122 Stat. 3016, 3017–38 (2008).

433. According to the American Association of Poison Control Centers, children (defined as less than or equal to twenty years of age) constituted approximately 65% of all reported cases of poisoning in 2008, while children under six constituted approximately 52% of cases. Alvin C. Bronstein et al., *2008 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 26th Annual Report*, 47 CLINICAL

adults, and the potentially greater sensitivity of children to some chemicals,<sup>434</sup> lawmakers must pay significant attention to this issue when drafting household chemical labeling legislation. Labeling on the front of packaging, potentially employing colors and symbols to convey the dangerous characteristics, could serve this goal.<sup>435</sup> As part of a broader instructional campaign aimed at children and parents, the colors and symbols could serve as a valuable educational tool, something that some critics believe could improve awareness of proper nutrition in connection with food labeling.<sup>436</sup>

While children represent one of the most important vulnerable groups that regulators must take into account, other groups also require consideration.<sup>437</sup> Studies indicate that while older consumers do consult nutrition labels when shopping, their usage rates and ability to interpret the information lag behind those of younger consumers.<sup>438</sup> Studies also suggest that educational programs aimed

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TOXICOLOGY 911, 923 (2009). According to the CDC, “[e]very day, 374 children in the United States ages 0 to 19 are treated in an emergency department, and two children die, as a result of being poisoned.” CENTERS FOR DISEASE CONTROL & PREVENTION, U.S. DEP’T OF HEALTH & HUMAN SERVS., POISONING FACT SHEET, available at [http://www.cdc.gov/safchild/Fact\\_Sheets/Poisoning-Fact-Sheet-a.pdf](http://www.cdc.gov/safchild/Fact_Sheets/Poisoning-Fact-Sheet-a.pdf).

434. See generally James V. Bruckner, *Differences in Sensitivity of Children and Adults to Chemical Toxicology: The NAS Panel Report*, 31 REG. TOXICOLOGY PHARMACOLOGY 280 (2000); Carl F. Cranor, *Do You Want to Bet Your Children’s Health on Post-Market Harm Principles?: An Argument for a Trespass or Permission Model for Regulating Toxicants*, 19 VILL. ENVTL. L.J. 251, 256–69 (2008).

435. Some nongovernmental entities have already attempted to solve this problem. For example, the nationwide “Mr. Yuk” campaign administered by the Children’s Hospital of Pittsburgh distributes stickers featuring a green face sticking its tongue out that are intended for application on poisonous chemical products. Children’s Hospital of Pittsburgh, *Mr. Yuk*, <http://www.chp.edu/CHP/mryuk> (last visited Sept. 20, 2011). As part of a comprehensive educational campaign, such symbols printed on the labels of household chemical products could help prevent accidental poisonings or other harmful effects to children’s health.

436. Javitt, *supra* note 122, at 358–60.

437. While this Note discusses a selection of vulnerable groups, it should not be read as discounting the importance of other factors. For example, experience with food labeling has suggested that differences may exist in nutrition labeling interpretation along race and gender lines. See, e.g., Padmini Shankar et al., *Dietary Intake and Health Behavior Among Black and White College Females*, 33 FAM. & CONSUMER SCI. RES. J. 159, 159–71 (2004); Mario F. Teisl et al., *Nutrition Labeling: Does the Message Reach the Consumer?*, ME. AGRIC. & FOREST EXPERIMENT STATION PUB. NO. 2231 6 n.3 (1998). Regulators may need to consider such groups in developing labeling schemes as well, although the particular methods of addressing labeling to those groups may be harder to determine.

438. Macon, *supra* note 395, at 51; Byrd-Bredbenner, *supra* note 395, at 37–41.

at older consumers would assist them in their use of the labeling.<sup>439</sup> Educational disadvantages may also have to be considered, as some studies have indicated may be the case with the Nutrition Facts Panel.<sup>440</sup> These studies, as well as those addressing children's use of labeling,<sup>441</sup> imply that a successful chemical labeling regime needs to incorporate a broader educational program that includes messaging targeted to specific consumer groups.<sup>442</sup>

The new labeling regulations should also address the needs of consumers who are particularly sensitive to chemicals, as the FALCPA does for people allergic to certain food ingredients.<sup>443</sup> While many chemicals may present a concern to the general population, and a proper labeling scheme should require listing of all ingredients in household products, some chemicals present risks to specific populations. People with allergies or sensitivities to certain chemicals form an obvious group similar to that covered by the FALCPA.<sup>444</sup> Infants and pregnant mothers present special cases, as

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439. Macon, *supra* note 395, at 51; Byrd-Bredbenner, *supra* note 395, at 41–42.

440. See, e.g., Russell L. Rothman et al., *Patient Understanding of Food Labels: The Role of Literacy and Numeracy*, 31 AM. J. PREVENTATIVE MED. 391, 394–97 (2006); Jonathan L. Blitstein & W. Douglas Evans, *Use of Nutrition Facts Panels Among Adults Who Make Household Food Purchasing Decisions*, 38 J. NUTRITION EDUC. & BEHAV. 360, 362–64 (2006); but see Anu Mitra et al., *Can the Educationally Disadvantaged Interpret the FDA-Mandated Nutrition Facts Panel in the Presence of an Implied Health Claim?*, 18 J. PUB. POL'Y & MARKETING 106, 113–14 (1999).

441. Javitt, *supra* note 122, at 358–61.

442. Some household chemical education programs, generally focused on the issue of accidental poisoning, already exist on the federal level. See, e.g., Ctrs. for Disease Control & Prevention, *Protect the Ones You Love: Child Injuries are Preventable*, <http://www.cdc.gov/safekid/Poisoning/index.html> (last visited Sept. 20, 2011) (CDC website containing poisoning prevention educational materials aimed at children); Env'tl. Prot. Agency, *Prevent Poisonings in Your Home*, <http://www.epa.gov/pesticides/health/poisonprevention.htm> (last visited Sept. 20, 2011) (EPA website containing poisoning prevention educational materials focusing on pesticides); Health Res. & Servs. Admin., U.S. Dept. of Health & Human Servs., *Poison Help*, <http://poisonhelp.hrsa.gov/resources/index.html> (last visited Sept. 20, 2011) (Health Resources and Services Administration website containing poisoning prevention educational materials aimed at both children and older adults).

443. Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108-282, 118 Stat. 891 (2004); see *supra* notes 117–21 and accompanying text.

444. A 1999 study found that 15.9% of people surveyed considered themselves to be “allergic or unusually sensitive to everyday chemicals,” while 6.3% reported that a doctor had informed them that they had “environmental illness or multiple chemical sensitivity.” Richard Kreutzer et al., *Prevalence of People Reporting Sensitivities to Chemicals in a Population-based Survey*, 150 AM. J. EPIDEMIOLOGY 1, 4 (1999). The FHSA, and the regulations issued pursuant to it, do address chemicals with a “[s]ignificant potential for causing hypersensitivity.”

many chemicals not ordinarily considered to require particular caution can cause negative health effects to expectant mothers, developing children, and fetuses.<sup>445</sup> The new labeling regulations should provide for notice to vulnerable groups such as these, whether through slogans, logos, or warning messages, when a product contains a chemical posing a proven hazard to them, or, alternatively, when a product has been proven not to pose a risk.<sup>446</sup>

### C. Uniformity

One of the greatest strengths of the “Nutrition Facts” labeling scheme stems from its ubiquitous and uniform placement and format

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16 C.F.R. § 1500.3(c) (2009); 15 U.S.C. § 1261(k) (2006). However, while the ingredients themselves may have to be listed if they have been proven to meet the definition of a “strong sensitizer” under 15 U.S.C. § 1261(k) and may have to carry some “affirmative statement” of their hazard as a sensitizer, the current regulations contain the same flaws as previously discussed in that they fail to identify many problematic chemicals, particularly if evidence of their effects is uncertain. 15 U.S.C. § 1261(k), (p) (2006). Nor has the CPSC or the FDA established any firm definitions of commonly used labeling terms, such as “hypoallergenic,” “unscented,” “fragrance-free,” “allergy-tested,” “nonirritating,” “dermatologist-tested,” or “sensitivity-tested” that could assist consumers in purchasing products less likely to cause allergic reactions as well as prevent manufacturers from making misleading claims. JULIE GABRIEL, *THE GREEN BEAUTY GUIDE: YOUR ESSENTIAL RESOURCE TO ORGANIC AND NATURAL SKIN CARE, HAIR CARE, MAKE-UP, AND FRAGRANCES* 31 (2008); Pamela L. Scheinman, *The Foul Side of Fragrance-Free Products: What Every Clinician Should Know about Managing Patients with Fragrance Allergy*, 41 J. AM. ACAD. DERMATOLOGY 1020, 1020–24 (1999).

445. Numerous studies have associated exposure to various ingredients in household chemical products during pregnancy and child development with health problems and developmental defects in children. *See, e.g.*, Theo Colburn, *Neurodevelopment and Endocrine Disruption*, 112 ENVTL. HEALTH PERSPS. 944 (2004); Andersen et al., *supra* note 327; Apelberg et al., *supra* note 327; Arnold et al., *supra* note 344; Bornehag et al., *supra* note 318; Bowen & Hannigan, *supra* note 340; Carruthers & Foster, *supra* note 315; Cho et al., *supra* note 315; Fei et al., *supra* note 327; Fei et al., *supra* note 329; Lottrup et al., *supra* note 315; Main et al., *supra* note 315; Sherriff et al., *supra* note 356; Swan et al., *supra* note 312; Swan et al., *supra* note 315; Washino et al., *supra* note 327; Win-Shwe & Fujimaki, *supra* note 341, at 96; ENVTL. WORKING GROUP, *supra* note 361; HOULIHAN et al., *supra* note 361; SCHREDER, *supra* note 361; Adibi et al., *supra* note 361; Kato et al., *supra* note 361; Reiner et al., *supra* note 361; Sathyanarayana et al., *supra* note 361; Silva et al., *supra* note 361; Ye et al., *supra* note 361.

446. Regulations issued by the governing authority under the new labeling program could accomplish this goal in part through defining terms, such as “hypoallergenic,” that would indicate the safety of a product for use by a particular vulnerable group, as the FALCPA did for food allergens. *See supra* notes 117–21 and associated text.

on all food packaging.<sup>447</sup> Unfortunately, the division of authority under the various chemical regulation laws may hamper progress toward similar uniformity for household chemical labeling.<sup>448</sup> Without either extensive and complicated interagency cooperation, or a consolidation of authority under one agency, the kind of ubiquitously designed and placed labeling represented by the “Nutrition Facts” label may be harder to achieve.<sup>449</sup> If each agency developed its own labeling scheme, the labeling for cosmetic products would likely differ in format, placement, and mandated information from the labeling for household cleaning products, which in turn would differ from the labeling for pesticides. This would require consumers to learn three separate labeling schemes, would create a greater likelihood of confusion, and would involve inefficient duplicative efforts. Ideally, authority for the labeling of all household chemical products, including cosmetics and pesticides, would be vested in a single agency.<sup>450</sup> However, given institutional ossification

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447. Kessler et al., *supra* note 79, at 14. Congress in drafting the NLEA had a particular interest in ensuring uniform labeling. See Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, § 6, 104 Stat. 2353, 2362 (1990) (titled “National Uniform Nutrition Labeling”).

448. For example, the CPSC places authority over labeling of most chemical products under the CPSC, but the FIFRA places authority over labeling of pesticides under the EPA and the FD&C Act places authority over labeling of cosmetics under the FDA. Consumer Product Safety Act, Pub. L. No. 92-573, § 3, 86 Stat. 1207, 1208 (1972); Federal Insecticide, Fungicide, and Rodenticide Act, Pub. L. No. 80-104, § 2, 61 Stat. 163, 163 (1947); Reorg. Plan No. 3 of 1970, 35 Fed. Reg. 15,623 (Oct. 6, 1970); Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, § 701, 52 Stat. 1040, 1055 (1938). Even the examples of proposed legislation previously discussed—the HPLA, the SCA of 2011, the KSCA, the TCSCA, and the SCA of 2010—would place authority over disclosure of chemical ingredient information under different agencies, the HPLA under the CPSC, the SCA of 2011 under the FDA, and the KSCA, the TCSCA, and the SCA of 2010 under the EPA. Toxic Chemicals Safety Act of 2010, H.R. 5820, 112th Cong. (2010); Safe Chemicals Act of 2010, S. 3209, 112th Cong. (2010); Household Product Labeling Act, H.R. 3057, 111th Cong. § 2 (2009); Household Product Labeling Act, S. 1697, 111th Cong. § 2 (2009); Kid-Safe Chemicals Act, H.R. 6100, 110th Cong. § 512 (2008); Kid-Safe Chemicals Act of 2008, S. 3040, 110th Cong. § 512 (2008); Safe Cosmetics Act of 2011, H.R. 2359, 112th Cong. § 2 (2011).

449. The problem of interagency cooperation in the enforcement of environmental laws has frequently come up in relation to a broad range of agency activities. See, e.g., ROBERT V. PERCIVAL ET AL., ENVIRONMENTAL REGULATION: LAW, SCIENCE, AND POLICY 96 (6th ed. 2009); RICHARD W. WATERMAN ET AL., BUREAUCRATS, POLITICS, AND THE ENVIRONMENT 13–14 (2004); Stefan R. Falke, *Environmental Data: Finding It, Using It, and Sharing It*, 9 J. URB. TECH. 111, 121–23 (2002).

450. As currently written, the HPLA would amend the FHS Act to mandate labeling for “household cleaning product[s] or similar product[s],” thus likely perpetuating the present



and possible disruption to the enforcement of other aspects of the laws containing the labeling provisions, consistent labeling of household chemicals across all product types would probably require extensive inter-agency cooperation.

Preemption of state labeling laws would also play a substantial role in the design of federal labeling regulations, both in ensuring consistent labeling regulations and in acquiring some industry support for regulation.<sup>451</sup> The NLEA preemption provisions have ensured that the federally-required information presented under the NLEA has appeared without potentially confusing information required under state laws.<sup>452</sup> This has displaced the previous patchwork of state regulation that both manufacturers and consumers sought to end.<sup>453</sup> The CPSA and the FIFRA contain express preemption clauses,<sup>454</sup> assuming, as the HPLA would,<sup>455</sup> that

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division of agency responsibilities under that act, because neither the FHSA nor the phrase “household cleaning product[s]” covers cosmetics or pesticides. H.R. 3057 § 2; S. 1697 § 2.

451. *See supra* note 275. However, the preemption of state labeling laws would not necessarily require preemption of state testing, disclosure, and green chemistry efforts. *See supra* notes 261–99.

452. *Id.*; *see also* Scarbrough, *supra* note 87, at 47–48 (discussing the effect of NLEA preemption on promoting national food labeling uniformity). While state labeling schemes such as the one administered in California under Proposition 65 can have a role in informing consumers in the absence of federal regulation, the presence of state warnings alongside federal warnings could lead to confusion, a complaint common to nutritional labeling prior to the NLEA. Kessler et al., *supra* note 79, at 14; *see also* Scarbrough, *supra* note 87, at 47–48. Manufacturers selling chemical products nationwide would also have to either develop separate labels for each state, or design one labeling scheme that complied with the shifting demands of the laws of all fifty states, an understandably daunting task. *See supra* notes 261–99.

453. *See supra* note 275; *see also* Kessler et al., *supra* note 79, at 14; Scarbrough, *supra* note 87, at 47–48.

454. Consumer Product Safety Act, 15 U.S.C. § 2075(a) (2006); Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136v(b) (2006). The CPSA preemption clause reads:

Whenever a consumer product safety standard under this chapter is in effect and applies to a risk of injury associated with a consumer product, no State or political subdivision of a State shall have any authority either to establish or to continue in effect any provision of a safety standard or regulation which prescribes any requirements as to the performance, composition, contents, design, finish, construction, packaging, or labeling of such product which are designed to deal with the same risk of injury associated with such consumer product, unless such requirements are identical to the requirements of the Federal standard.

15 U.S.C. § 2075(a). The FIFRA clause similarly bars all state labeling that differs from the federal requirements, mandating that no state may “impose or continue in effect any

household chemical labeling authority would fall predominantly under the CPSC, conflicting state laws would not interfere with the federal scheme.<sup>456</sup> However, in *Wyeth v. Levine*, the Supreme Court recently held that the FD&C Act does not bar tort claims based on state law.<sup>457</sup> Therefore, either the new labeling regulations may have to transfer authority for labeling of cosmetics away from the FDA under the FD&C Act, or they may have to contain their own express preemption language covering all product types.

#### D. Clarity

The standardized format of the “Nutrition Facts” label and its prominent placement on food packaging has provided consumers with quick and easy access to the information presented.<sup>458</sup> In keeping with the uniformity theme previously identified, the label appears in the same format and includes the same information on all food packages, and provides all important government-mandated health information in one location.<sup>459</sup> The new household chemical product label should adopt a similar structure, listing all ingredients, cautionary statements, and other useful health information in one location on the product’s label. Regulators should pay careful attention to the label design in order to ensure that it provides the

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requirements for labeling or packaging in addition to or different from those required” by the FIFRA. 7 U.S.C. § 136v(b).

455. H.R. 3057 § 2(c); S. 1697 § 2(c).

456. This would obviously also determine the effect of success under lawsuits such as that brought under the Conservation Law of New York. See *supra* note 289.

457. See *Wyeth v. Levine*, 129 S. Ct. 1187 (2009).

458. Derby, *supra* note 385, at 387; Christine Moorman, *A Quasi-Experiment to Assess the Consumer and Informational Determinants of Nutrition Information Processing Activities: The Case of the Nutrition Labeling and Education Act*, 15 J. PUB. POL’Y & MARKETING 28, 41–42 (1996). The Nutrition Facts label has become a “recognized and highly regarded icon for providing consumer information,” and is the inspiration for numerous other labels and designs. Taylor & Wilkening, *supra* note 91, at 441–42.

459. Food & Drug Admin., *How to Understand and Use the Nutrition Facts Label*, <http://www.fda.gov/Food/LabelingNutrition/ConsumerInformation/ucm078889.htm> (last visited Sept. 20, 2011). The Nutrition Facts label always appears on “that part of the label immediately contiguous and to the right of the principal display panel as observed by an individual facing the principal display panel,” but if that panel cannot accommodate the information, then the panel “immediately contiguous and to the right of this part of the label may be used.” 21 C.F.R. § 101.2(a) (2009).

same benefits as the “Nutrition Facts” label.<sup>460</sup> Cosmetics, cleaning products, pesticides, and all other household chemicals should bear the same label in the same format, allowing consumers to easily find the information they seek.<sup>461</sup>

Consistent and clear use of descriptors, measurement units, and similar data points also helps consumers interpret the “Nutrition Facts” label.<sup>462</sup> For example, people may properly refer to vitamin C as L-ascorbic acid, 2-oxo-L-threo-hexono-1,4-lactone-2,3-enediol, and vitamin C, among other names.<sup>463</sup> Only the name “vitamin C,” however, would likely resonate with consumers, and that name always appears on food product labels.<sup>464</sup> Household chemical labels should similarly identify ingredients with names that consumers will recognize, particularly when labeling ingredients posing potential hazards to human health. Even where such names do not exist, however, labels should consistently identify the chemical components with the same name on every product.<sup>465</sup> Also, as the FDA learned in adjusting its nutrition label to include percentages of the U.S. Recommended Daily Allowance, consumers must understand the units of measurement employed and the units must clearly represent the quantities that they identify.<sup>466</sup> Chemical product labels must also

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460. Taylor & Wilkening, *supra* note 91, at 441–42.

461. Studies concerning the Nutrition Facts label support the contention that locating all relevant consumer health information in one position on the label improves access to that information. *See, e.g.*, Moorman, *supra* note 458, at 37 (finding that the NLEA label improved both acquisition and comprehension of nutrition information).

462. *Id.* at 41–42.

463. *See, e.g.*, Material Measurement Lab., Nat’l Inst. Of Standards & Tech., *L-Ascorbic acid*, [http://webbook.nist.gov/cgi/inchi/InChI%3D1S/C6H8O6/c7-1-2\(8\)5-3\(9\)4\(10\)6\(11\)12-5/h2%2C5%2C7-10H%2C1H2](http://webbook.nist.gov/cgi/inchi/InChI%3D1S/C6H8O6/c7-1-2(8)5-3(9)4(10)6(11)12-5/h2%2C5%2C7-10H%2C1H2) (last visited Sept. 20, 2011) (listing alternative names for L-Ascorbic acid).

464. 21 C.F.R. § 101.9(c)(8)(iv) (2009).

465. A number of different options exist for the household chemical ingredient nomenclature; for example, the industry’s voluntary ingredient disclosure program permits use of the “International Nomenclature Cosmetic Ingredient (INCI) name, and/or the International Union of Pure and Applied Chemistry (IUPAC) name, Chemical Abstract Service (CAS) name, Consumer Specialty Products Association (CSPA) Dictionary name, and/or the common chemical name.” AMERICAN CLEANING INSTITUTE, CPICI, *supra* note 275. Environmental organizations have criticized this aspect of the program due to the confusion caused by the lack of uniform terms. WOMEN’S VOICES FOR THE EARTH, CONSUMERS TO GET MORE INFORMATION, *supra* note 275.

466. Kessler et al., *supra* note 79, at 15.

present their information in forms easily understood by the reasonable consumer.

### *E. Education*

The success of the nutrition labeling scheme in the United States has occurred in part due to the improved understanding by consumers regarding the role that nutrition plays in maintaining health.<sup>467</sup> The nutritional labeling scheme included nutrition education as a central theme,<sup>468</sup> and Congress and the FDA saw the NLEA as a means of disseminating the increased scientific knowledge regarding the relationship between diet and health.<sup>469</sup> While much remains uncertain regarding the relationships between household chemical exposure and various human health and environmental harms, educational campaigns that highlight the relationships, much like the FDA and USDA programs that increased consumer knowledge regarding some aspects of nutrition,<sup>470</sup> could allow consumers to make more informed choices. Accompanied by a labeling program corresponding to the substances, health issues, and environmental concerns emphasized by the educational program, consumer knowledge could improve, and their ability to understand the risks they assume with household chemical purchase and use would increase.<sup>471</sup> The same educational goals and aspirations pursued by Congress and the FDA in drafting the NLEA should apply to the new chemical labeling regime.

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467. See Joan F. Guthrie et al., *What People Know and Do Not Know about Nutrition*, in AMERICA'S EATING HABITS: CHANGES AND CONSEQUENCES 243, 246–47 (Elizabeth Frazao ed., 1999), available at <http://www.ers.usda.gov/publications/aib750/aib750m.pdf>.

468. Christine L. Taylor & Virginia L. Wilkening, *How the Nutrition Food Label Was Developed, Part 2: The Purpose and Promise of Nutrition Claims*, 108 J. AM. DIETETIC ASS'N 618, 619 (2008).

469. Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision, 55 Fed. Reg. 29,487, 29,490 (July 19, 1990).

470. The USDA and FDA nutrition programs have succeeded in increasing knowledge of such nutritional factors as the relationship between diet and heart disease. Guthrie et al., *supra* note 467, at 246–47. However, studies have also shown that education concerning more complex nutritional issues sometimes fails. *Id.* at 272. Nonetheless, the educational efforts have provided Americans with a basic understanding of the importance of nutrition to health and have stimulated discussion of nutrition issues in public discourse.

471. RODRICKS, *supra* note 368, at 318–19.

### F. Testing, Standards, and Enforcement

The new labeling legislation will only succeed if the responsible agencies enforce it adequately. Adequate enforcement will require that a number of changes to the current testing and standards be made. Principal among these is pre-market testing for household chemical products and their ingredients.<sup>472</sup> Under the present regulatory regime, both cosmetics regulated by the FDA and other household chemicals regulated by the CPSC and the EPA usually do not undergo testing prior to sale.<sup>473</sup> In contrast, manufacturers must obtain permission from the FDA before using any new food additives.<sup>474</sup> The FDA has defined new food additives as “unsafe for their intended uses unless and until they are proven ‘safe’ on the basis of scientific data and information.”<sup>475</sup> This has resulted in a system that, while occasionally controversial, in part due to the list of “generally recognized as safe” additives in use prior to the Food Additives Amendment for which the FDA has not required testing,<sup>476</sup> has generally ensured that new food ingredients receive some safety

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472. Denison, *supra* note 213, at 10,022–23.

473. Rawlins, *supra* note 17, at 11–16; *see also* ENVTL. HEALTH STRATEGY CENTER, *THAT’S A KILLER LOOK: A STUDY OF CHEMICALS IN PERSONAL CARE PRODUCTS 1* (2010), available at <http://www.preventharm.org/Images/132/ACHM%20Cosmetics%20Report.pdf> (claiming that “[o]ut of 12,500 different ingredients in cosmetics and personal care products, nearly 90% have not been assessed for safety by any publicly accountable entity.”); JANET GRAY, BREAST CANCER FUND, *STATE OF THE EVIDENCE: THE CONNECTION BETWEEN BREAST CANCER AND THE ENVIRONMENT* 84 (2010), available at <http://www.breastcancerfund.org/assets/pdfs/publications/state-of-the-evidence-2010.pdf> (claiming that only 11 percent of chemicals used in cosmetics have undergone testing); Letter from Richard Wiles, Exec. Dir. of Env’tl. Working Grp., to Andrew C. von Eschenbach, Comm’r of Food & Drugs, U.S. Food & Drug Admin. (Sept. 26, 2007), available at [http://www.ewg.org/files/EWGviolanalysis\\_092607.pdf](http://www.ewg.org/files/EWGviolanalysis_092607.pdf) (claiming 98 percent of cosmetics products tested “contain one o[r] more ingredients never publicly assessed for safety”).

474. 21 U.S.C. § 348 (2006).

475. Alan M. Rulis & Joseph A. Levitt, *FDA’s Food Ingredient Approval Process: Safety Assurance Based on Scientific Assessment*, 53 REG. TOXICOLOGY PHARMACOLOGY 20, 21 (2008).

476. Frederick H. Degan, *Rethinking the Applicability and Usefulness of the GRAS Concept*, 46 FOOD DRUG COSM. L.J. 553, 582 (1991) (arguing that the GRAS concept retains usefulness as a means for the FDA to concentrate its resources on important issues); Rulis & Levitt, *supra* note 475, at 26–27; *see also* Lars Noah & Richard A. Merrill, *Starting from Scratch: Reinventing the Food Additive Approval Process*, 78 B.U. L. REV. 329 (1998) (recognizing the usefulness of the GRAS concept but advocating reforms in light of challenges posed by a changing food market).

evaluation before entering the food supply. Similar testing requirements, such as those proposed under the TCSA and the SCA of 2010,<sup>477</sup> should apply to the household chemical industry to ensure that ingredients are evaluated before entering consumers' homes. Whatever the merits of the "generally recognized as safe" concept for food additives, however, testing for household chemicals must include chemicals already in use as well as newly introduced ones, since so few of them have received official evaluation, and since scientific evidence suggests the need for such evaluation.<sup>478</sup>

The TCSA and the SCA of 2010 provide a blueprint for many of the necessary elements of testing and standards reform. To ensure product safety, new legislation must place the burden on the chemical industry to demonstrate the safety of their household chemical products through sufficient information to show they meet applicable safety standards, rather than on the government to show their toxicity.<sup>479</sup> Manufacturers must provide sufficient information for regulators to assess the toxicity of their products.<sup>480</sup> Legislation must provide for the testing of both newly created and in use but untested chemicals and mixtures, a principle served by the creation of priority lists under the TCSA and the SCA.<sup>481</sup> The government should establish safety standards sufficient to protect public health and the environment with at least an adequate margin of safety.<sup>482</sup> As under

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477. Toxic Chemicals Safety Act of 2010, H.R. 5820 § 4(b), 112th Cong. (2010); Safe Chemicals Act of 2010, S. 3209 § 5(b), 112th Cong. (2010).

478. See *supra* notes 215, 473.

479. H.R. 5820 § 6; S. 3209 § 7. Environmental groups, the EPA, and even industry trade groups have recognized the need to place more of the burden on manufacturers to provide support for the safety of their products. See, e.g., Denison, *supra* note 213, at 10022–23; AM. CHEMISTRY COUNCIL, 10 PRINCIPLES FOR MODERNIZING TSCA, available at [http://www.americanchemistry.com/s\\_acc/sec\\_mediakits.asp?CID=2178&DID=9938](http://www.americanchemistry.com/s_acc/sec_mediakits.asp?CID=2178&DID=9938); ENVTL. PROT. AGENCY, ESSENTIAL PRINCIPLES FOR REFORM OF CHEMICALS MANAGEMENT LEGISLATION (2009), available at <http://www.epa.gov/opptintr/existingchemicals/pubs/principles.pdf>; HILTS, *supra* note 32, at 54. This bears some similarity to the conditions following passage of the 1906 PFDA, which placed the burden on the government to prove claims false. HILTS, *supra* note 32, at 54.

480. Wilson & Schwarzman, *supra* note 19, at 1205.

481. H.R. 5820 § 6; S. 3209 § 7; Denison, *supra* note 213, at 10023–24.

482. The "adequate margin of safety" standard is employed for National Ambient Air Quality Standards under the Clean Air Act. 42 U.S.C. § 7409(b)(1) (2010). The TCSA employs what could be read as a somewhat more restrictive standard, requiring that "with regard to public health, there is a reasonable certainty that no harm will result, including to vulnerable

the TCSA and the SCA of 2010, safety determinations and the support for them must be made publicly available.<sup>483</sup> However, as much of the science in this area is ambiguous and uncertain, testing and standards on their own will not likely be sufficient to serve the needs of consumers.<sup>484</sup> To properly protect consumers, testing and standards must be accompanied by sufficient point-of-purchase ingredient disclosure so that consumers can choose which risks to accept.

## VI. CONCLUSION

Over the course of the twentieth century, the American nutritional labeling program has evolved into an effective and informative method of protecting consumers' rights to choose what to put into their bodies.<sup>485</sup> As the links between people's health and the food they eat have become more evident, the regulations ensuring that consumers have the power to make appropriate decisions regarding that food have adapted to accommodate that new evidence.<sup>486</sup> Room for improvement remains, but the essential structures and

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populations; and . . . the public welfare is protected." H.R. 5820 § 6. The SCA of 2011 also applies a "reasonable certainty of no harm standard." H.R. 2359 § 611(7). This is essentially the same standard employed under the FQPA. Food Quality Protection Act of 1996, Pub. L. No. 104-170, § 404, 110 Stat. 1489, 1514 (1996). Industry groups have questioned the extension of this standard into chemical testing reform, arguing that it would place inappropriate burdens on the manufacture of chemicals that are not intended for consumption, and have advocated for a "safe for use" standard. Soc'y of Chem. Mfrs. & Affiliates, *Safe for Use*, <http://www.socma.com/GovernmentRelations/index.cfm?subSec=26&articleID=2118> (last visited Sept. 20, 2011). Given the uncertainty of much of the science in this area, an absolute certainty standard would likely prove too restrictive in practice. RODRICKS, *supra* note 368, at 284–90, 309; Sharpe, *supra* note 379, at 447; *Safe for Use, supra*. The appropriate standard for TSCA reform remains in dispute. For an argument in favor of a "reasonable certainty" standard, see Rawlins, *supra* note 17, at 46–50.

483. H.R. 5820 §§ 6, 8; S. 3209 §§ 7, 9.

484. Completely banning substances on the basis of the slightest uncertainty would also not serve the interests of consumers, as many of these chemicals serve useful purposes in improving the performance and quality of products. It could also cripple the chemical industry, as providing absolute evidence of safety may be impossible in many cases. RODRICKS, *supra* note 368, at 284–90, 309; Sharpe, *supra* note 379, at 447; *see supra* notes 379–84 and accompanying text.

485. *See supra* note 385.

486. *See supra* Part II.

philosophies behind the nutritional labeling regime stand as a model for other labeling programs.

At the same time, the regulatory treatment of household chemical products takes away consumers' ability to select the chemical exposure risks they are willing to assume.<sup>487</sup> Lax enforcement by administrative agencies and a lack of affirmative Congressional action have deprived consumers of the knowledge they need.<sup>488</sup> The regulations and statutes maintained by the CPSC, the FDA, the EPA, and other agencies do not give consumers sufficient data to make educated decisions, and demand reform.<sup>489</sup>

The nutritional labeling scheme suggests a path forward, providing an example for future household chemical regulation. Mandatory, nationwide, and uniform labeling, reinforced by rigorous testing standards, define the necessary elements of a new labeling regime.<sup>490</sup> Proper attention to the disparate needs of vulnerable consumer groups requires labeling that addresses differing medical concerns and knowledge gaps.<sup>491</sup> Consistent and effective enforcement of the new labeling scheme would provide consumers with the information that they need in order to decide whether the benefits of the chemicals they use outweigh the hazards that they present.<sup>492</sup> The potential dangers accompanying many common household chemical ingredients demand nothing less.

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487. Dunagan et al., *supra* note 402, at 441–42.

488. *Id.*

489. *Id.*

490. *See supra* Part V.

491. *See supra* notes 430–46 and accompanying text.

492. *See supra* Part V.