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NatAgLaw@uark.edu · (479) 575-7646

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**Food Supplements Directive: An Attempt to  
Restore the Public Confidence in Food Law**

by

Fiona LeCong

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# Food Supplements Directive: An Attempt to Restore the Public Confidence in Food Law

## I. INTRODUCTION

The vitamin market in the United Kingdom (“UK”) was valued at £335 million in 2000<sup>1</sup> and was estimated to reach £362 million in 2005.<sup>2</sup> About twenty-one million Britons—a third of all women and a quarter of men—take supplements in the belief that they will improve their health.<sup>3</sup> When the Food Supplements Directive, Directive 2002/46/EC (“Food Supplements Directive”), was adopted by the European Parliament and Council on June 10, 2002,<sup>4</sup> it became the first Europe-wide legislation for food supplements.<sup>5</sup> Enactment of implementing legislation in the UK would mean stricter regulation, higher testing expenses for manufacturers of food supplements in order to meet these regulations, and the removal of many vitamins and minerals from store shelves.<sup>6</sup> Because the Food Supplements Directive could lead to the banning of up to three hundred nutrients and nutrient sources in the UK, there has been considerable outrage and dismay among consumers and manufacturers of food

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1. Christine Eberhardie, *Food Supplements and Herbal Medicines*, NURSING STANDARD, Sept. 28, 2005, at 52, available at <http://www.nursing-standard.co.uk/archives/ns/vol20-03/pdfs/v20n03p5256.pdf>.

2. Sam Lister, *Health Groups Lose Appeal on EU Food Supplement Ban*, THE TIMES, July 13, 2005, available at <http://www.timesonline.co.uk/article/0,,2-1691933,00.html> (impact estimated by John Bowis, Tory Health spokesman in the European Parliament).

3. Alastair Jamieson, *Vitamins: Too Bitter a Pill for Us to Swallow or Should We Just Keep Taking the Tablets?*, THE SCOTSMAN, July 16, 2005, at 26.

4. Council Directive 2002/46 on the Approximation of the Laws of the Member States Relating to Food Supplements, 2002 O.J. (L 183) 51 (EC) [hereinafter Food Supplements Directive].

5. DEBRA HOLLAND & HELEN POPE, EU FOOD LAW AND POLICY 93 (2004).

6. See Graham Hiscott, *EU Court Tightens Rules on Vitamins; Hundred of Popular Pills May be Cleared Off Shelves*, THE EXPRESS (London), July 13, 2005, at 11.

supplements.<sup>7</sup> Two separate cases were quickly brought before the High Court of Justice of England and Wales, challenging the validity of the Food Supplements Directive.<sup>8</sup> These cases, *The Queen*, on the application of: *Alliance for Natural Health and Nutri-Link Ltd v. Secretary of State for Health*, and *The Queen*, on the application of: *National Association of Health Stores Health Food and Manufacturers Ltd. v. Secretary of State for Health and National Assembly for Wales*, were referred to the European Court of Justice (“ECJ”) for a preliminary ruling and were joined together.<sup>9</sup>

This Note argues that the ECJ was correct in its decision to uphold a Europe-wide legislation on food supplements, ruling in favor of consumer protection over free movement of goods within the European Community (“Community”). Part II lays out the general background for the Food Supplements Directive. Part III outlines the relevant facts in *Alliance for Natural Health*. Part IV uses ECJ case law to argue that the Food Supplements Directive is proportionate to the Community’s goal of public safety. Part V introduces the public policy rationales for instituting such a regulation and delineates the failures—which the Food Supplements Directive promises to overcome—of the U.S. Dietary Supplement Health and Education Act (“DSHEA”). Part VI concludes that the Food Supplements Directive is consistent with the Community’s goal of re-establishing public confidence in its food supply.

## II. BACKGROUND

Until recently, there was no Europe-wide legislation on food supplements.<sup>10</sup> Food supplements were regulated differently by each Community Member State, with some adopting a very liberal approach similar to that of the United States.<sup>11</sup> Because food supplements do not clearly fall under either the food or medicine regulatory categories, they were sometimes regulated as medicines

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7. See *Lister*, *supra* note 2, at 2.

8. 2004 O.J. (C 118) 33.

9. *Id.*

10. Nicole Coutrelis, *The Legal Status and Regulatory Context of “Health Foods” in the European Union*, 58 *FOOD & DRUG L.J.* 35, 38 (2003).

11. See *id.*

and other times as food depending on the product and its function and/or presentation.<sup>12</sup>

In the late 1990s, there were several occurrences of food contamination due to decisions by the Community that lacked support by full scientific evidence.<sup>13</sup> These incidents brought about a general public distrust in all action by the Community in the field of consumer protection.<sup>14</sup> In response, the European Commission (“Commission”) issued the White Paper on Food Safety in January 2000, which reinforced its commitment to re-establishing public confidence in its food supply, food science, food law, and food controls.<sup>15</sup> The Commission also recognized the “need to create a coherent and transparent set of food safety rules”<sup>16</sup> in order to offer consumers a wide range of safe and high quality products coming from all Member States.<sup>17</sup> As part of their “Action Plan on Food Safety,” the Commission planned to propose a directive on food supplements by March 2000, with the objective of laying down common criteria for marketing concentrated sources of nutrients.<sup>18</sup>

In June 2002, the European Parliament and Council adopted the Food Supplements Directive, which harmonizes the laws of Member States relating to food supplements.<sup>19</sup> Under the Food Supplements Directive, food supplements are defined as:

[F]oodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken

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12. *Id.*

13. See James Stamps, *Trade in Biotechnology Food Products*, 43 INT’L ECON. REV. 5, 9 (2002).

14. Paulette Kurzer, *European Citizens Against Globalization: Public Health and Risk Perceptions 17-18* (Apr. 2004) (working paper, on file with the Martindale Center at the College of Business and Economics at Lehigh University), <http://www.lehigh.edu/martindale/publications/kurzer.pdf>.

15. *Commission White Paper on Food Safety*, at 7, COM (1999) 719 final (Jan. 12, 2000).

16. *Id.* at 22.

17. *Id.* at 6.

18. *Id.* at 48.

19. Food Supplements Directive, *supra* note 4.

in measured small unit quantities.<sup>20</sup>

The Food Supplements Directive was adopted on the basis of Article 95(3) of the Treaty Establishing the European Community, which provided that the Commission and also the European Parliament and Council in their proposals concerning health, safety, environmental protection, and consumer protection, are to set a high level of protection and take into account any new development based on scientific facts.<sup>21</sup>

The Food Supplements Directive focuses on the substances used in manufacturing vitamins and minerals, the maximum dosage allowed for intake, and the labeling, presentation, and advertising of food supplements.<sup>22</sup> The Food Supplements Directive explicitly prohibits references to the food supplements' ability to treat or cure human disease when marketing food supplements.<sup>23</sup> It was written with two basic principles in mind: (1) the consumer should be protected from unsafe products and should not be misled, and (2) food should not be represented as medicine.<sup>24</sup> Because European legislation overrides domestic legislation, all Member States, including the UK, must enforce the Food Supplements Directive.<sup>25</sup>

The Food Supplements Directive allows only vitamins and minerals listed on the "positive list"<sup>26</sup> to be used for the manufacture of food supplements.<sup>27</sup> Anything not included on the "positive list" faces a Community-wide prohibition.<sup>28</sup> The "positive list" currently contains 112 substances that are fit for sale, including vitamin C, calcium, and iron.<sup>29</sup> Manufacturers of supplements that contain substances not included on the current "positive list" will find it difficult to get those substances added to

20. "Nutrients" are defined as vitamins and minerals. *Id.* art. 2.

21. Consolidated Version of the Treaty Establishing the European Community art. 95(3), Dec. 24, 2002, 2002 O.J. (C 325), available at <http://europa.eu.int/eur-lex/en/treaties/selected/livre221.html> [hereinafter EC Treaty].

22. Food Supplements Directive, *supra* note 4, arts. 4-6, at 53.

23. Coutrelis, *supra* note 10, at 39.

24. *Id.* at 36.

25. See Mike Abrahams, Ph.D., *European Directive on Food Supplements - A Disaster for the Health of the Nation?*, POSITIVE HEALTH, Mar. 2002, <http://www.positivehealth.com/permit/Articles/Nutrition/abrahams74.htm>.

26. These "positive lists" are listed as Annex I and II of the Food Supplements Directive.

27. Food Supplements Directive, *supra* note 4, art. 4, at 53.

28. *Id.*

29. *Id.* Annex II.

the list. The tests necessary for adding a substance to the “positive list” cost between £80,000 and £250,000 per product, which could cause some manufacturers to face bankruptcy.<sup>30</sup> Also, experience with the application process has shown that it can take two to three years to obtain good quality data on the safety of vitamins and minerals if the manufacturer starts from scratch.<sup>31</sup> Fearing that the difficulties facing manufacturers could result in the banning of many supplements currently in use, more than a million Britons have signed a petition against the Food Supplements Directive.<sup>32</sup> Over three hundred doctors and scientists have also signed a letter of protest to Prime Minister Tony Blair.<sup>33</sup> In addition, the campaign has received the backing of celebrities such as Paul McCartney, Elton John, and actress Jenny Seagrove who stated, “This directive is one of the silliest policies ever to come out of Europe.”<sup>34</sup>

However, in spite of all the protests, some have welcomed the Food Supplements Directive and its backing by the ECJ. Sue Davies, chief policy adviser at the consumer body, Which?, released the following statement in support of the Food Supplements Directive:

The decision means that, finally, people who take supplements will be properly protected. . . . It'll ensure that products are safe, that they contain forms of vitamins and minerals that offer some benefit, and that they are clearly labeled. Contrary to the many misleading reports put out by those wishing to promote and sell supplements free of controls to protect consumers, the directive is not anti-consumer choice. It will instead mean that at long last consumers can make<sup>35</sup> informed choices about the supplements they take.

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30. Hiscott, *supra* note 6.

31. Peter Berry Ottaway, *Dietary Supplements in the European Union – The Next Stages*, NUTRACEUTICALS INT'L, Oct. 21, 2005.

32. Lister, *supra* note 2, at 2.

33. *Id.*

34. Hiscott, *supra* note 6.

35. Press Release, Which?, ECJ Ruling on Food Supplements (July 12, 2005), [http://www.which.co.uk/press/press\\_topics/campaign\\_news/food/ECJ\\_ruling\\_food\\_supplements\\_press\\_release\\_571\\_56091.jsp](http://www.which.co.uk/press/press_topics/campaign_news/food/ECJ_ruling_food_supplements_press_release_571_56091.jsp).

Other campaigners, worried about the potential damage of over-using vitamins and minerals, also welcomed the ECJ's ruling.<sup>36</sup>

### III. FACTS

The Alliance for Natural Health, Nutri-Link Limited, the National Association of Health Stores, and Health Food Manufacturers Limited ("Claimants") applied to the High Court of Justice of England and Wales for leave to commence proceedings for judicial review of Articles 3, 4(1), and 15(b) of the Food Supplements Directive.<sup>37</sup> Together, these Articles prohibit trade within the Community of products that do not comply with the Food Supplements Directive, effective August 1, 2005.<sup>38</sup> These Articles also create a "positive list" for substances that are allowable for use in the manufacturing of food supplements.<sup>39</sup>

The High Court stayed the proceedings and referred the cases to the ECJ for a preliminary ruling.<sup>40</sup> The two cases were joined together.<sup>41</sup> On April 5, 2005, the Advocate General delivered his opinion, finding that the Food Supplements Directive is invalid because it infringes the principle of proportionality.<sup>42</sup> The Advocate General found that the Food Supplements Directive could not pass the proportionality test because basic principles of Community law, such as the requirements of legal protection, legal certainty, and sound administration, had not properly been taken into account.<sup>43</sup> However, the opinion of an Advocate General is merely persuasive; the final decision is made by the ECJ.<sup>44</sup> The ECJ noted that the proportionality test requires that the measure be necessary and proportionate in relation to the objective

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36. Hiscott, *supra* note 6.

37. Opinion of Advocate General, Joined Cases C-154/04 & C-155/04, *Alliance for Natural Health v. Sec'y of State for Health*, 2005 E.C.R. 1-6451, para. 1, available at <http://curia.eu.int/jurisp/cgi-bin/form.pl?lang=en&Submit=Submit&alldocs=alldocs&docj=docj&docop=docop&docor=docor&docjo=docjo&numaff=c-155%2F04&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100> [hereinafter *Opinion of Advocate General*].

38. *Id.* para. 2.

39. See Food Supplements Directive, *supra* note 4.

40. Opinion of Advocate General, *supra* note 37, para. 17.

41. *Id.* para. 19.

42. *Id.* para. 111.

43. *Id.*

44. Debra Huetting, *European Union: Food Supplements Directive Upheld*, MONDAQ BUS. BRIEFING, Feb. 22, 2006, <http://www.mondaq.com/article.asp?articleid=37982>.

pursued.<sup>45</sup> Upon review by the ECJ on July 12, 2005, the thirteen-judge panel found no infringement of the principle of proportionality and unanimously upheld the Food Supplements Directive.<sup>46</sup>

#### IV. CASE ANALYSIS

The Claimants challenged the Food Supplements Directive on multiple grounds including:

- (a) the inadequacy of Article 95 as a legal basis;
- (b) infringement of (i) Articles 28 and 30 of the EC Treaty and/or (ii) Articles 1(2) and 24(2)(a) of Regulation (EC) No 3285/94;
- (c) infringement of the principle of subsidiarity;
- (d) infringement of the principle of proportionality;
- (e) infringement of the principle of equal treatment;
- (f) infringement of Article 6(2) of the Treaty on European Union, read in the light of Article 8 of, and Article 1 of the First Protocol to, the European Convention on Human Rights, and of the fundamental right to property and/or the right to carry on an economic activity;
- (g) infringement<sup>47</sup> of Article 253 EC and/or the duty to give reasons.

The ECJ found that the Food Supplements Directive was not invalid for any of the reasons set forth by the claimants.<sup>48</sup> For purposes of this Note, only the ECJ's analysis of the principle of proportionality will be discussed in depth.

The principle of proportionality is a general principle of Community law.<sup>49</sup> The proportionality principle implies the need

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45. Joined Cases C-154/04 & C-155/04, *Alliance for Natural Health v. Sec'y of State for Health*, para. 51, available at <http://curia.europa.eu/jurisp/cgi-bin/form.pl?lang=en&Submit=Submit&alldocs=alldocs&docj=docj&docop=docop&docor=docor&docjo=docjo&numaff=&datefs=&datefe=&nomusuel=Alliance+for+Natural+Health+&domaine=&mots=&resmax=100> [hereinafter *Alliance for Natural Health*].

46. *Alliance for Natural Health*, *supra* note 45, para. 139.

47. *Id.* para. 22.

48. *Id.* para. 139.

49. Case C-210/00, *Kaserei Champignon Hofmeister GmbH & Co. KG v. Hauptzollamt Hamburg-Jonas*, para. 59, available at <http://curia.europa.eu/jurisp/cgi-bin/form.pl?lang=en&Submit=Submit&alldocs=alldocs&docj=docj&docop=docop&docor=docor&docjo=docjo&numaff=C-210%2F00&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100> [hereinafter *Kaserei*].



to strike a proper balance between competing interests.<sup>50</sup> When the ECJ faces a claim based on infringement of the proportionality principle, the Court must consider whether measures implemented through Community laws are appropriate for attaining the objective pursued and whether they go beyond what is necessary to achieve it.<sup>51</sup>

In *Alliance for Natural Health*, the two competing interests are the protection of the health and life of humans and the free movement of goods.<sup>52</sup> Thus, in applying the proportionality test to this case, the ECJ must ascertain whether the Food Supplements Directive, which prohibits trade in food supplements that do not comply with its provisions, is necessary and proportionate in relation to the objective of protecting human health.<sup>53</sup>

#### A. Was the Food Supplements Directive “Necessary”?

The ECJ traditionally has given great deference to the Community legislature in regards to measures entailing “political, economic and social choices on its part, and in which it is called upon to undertake complex assessments.”<sup>54</sup> It has found that measures relating to public health fall into this area of broad discretion.<sup>55</sup> Consequently, the ECJ has ruled that the legality of a measure adopted in the sphere of broad discretion can only be held invalid if the measure is “manifestly inappropriate” with regard to the objective that the competent institution is seeking to pursue.<sup>56</sup>

In *Ex parte British American Tobacco (Investments) Ltd*, Directive 2001/37/EC – Manufacture, Presentation and Sale of Tobacco Products (“Tobacco Directive”) was challenged for infringing the principle of proportionality. As in *Alliance for Natural Health*, a conflict existed between the interests of public health and the free movement of goods. The claimants argued that the ban on cigarette manufacture for export to non-member countries that are non-compliant with the requirements of the

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50. See P. VAN DIJK & G.J.H VAN HOOF, THEORY AND PRACTICE OF THE EUROPEAN CONVENTION OF HUMAN RIGHTS 537 (3d ed. 1998).

51. Kaserei, *supra* note 49, para. 59.

52. Alliance for Natural Health, *supra* note 45, para. 48.

53. *Id.* para. 52.

54. *Id.*

55. Case C-491/01, *The Queen v. Sec’y of State for Health*, 2002 E.C.R. I-11453, para. 123.

56. *Id.*

Tobacco Directive was not an appropriate method of accomplishing the Community's goal of preventing illegal trafficking of cigarettes.<sup>57</sup> In that case, even though the ECJ found that "the prohibition at issue does not [alone] make it possible to prevent the development of the illegal trade in cigarettes in the Community," it found that the measure was "likely to make an effective contribution to limiting the risk of growth in the illegal trafficking of cigarettes" and thus was not "manifestly inappropriate."<sup>58</sup>

In *Alliance for Natural Health*, the Claimants denied that the prohibition was necessary. They asserted that Articles 4(7) and 11(2) of the Food Supplements Directive give the Member States the power to restrict trade in food supplements that do not comply with their requirements and that a Community prohibition is thus superfluous.<sup>59</sup> Those Articles read as follows:

Article 4(7) - Notwithstanding paragraph 6, Member States may, in compliance with the rules of the Treaty, continue to apply existing national restrictions or bans on trade in food supplements containing vitamins and minerals not included in the ["positive list"].

Article 11(2) - Without prejudice to the Treaty, paragraph 1 [of Article 11] shall not affect national provisions which are applicable in the absence of Community acts adopted under this Directive.<sup>60</sup>

The ECJ found the Claimants' arguments to be irrelevant for the purpose of ascertaining whether or not the prohibition in Articles 3, 4(1), and 15(b) of the Food Supplements Directive is necessary;<sup>61</sup> thus, the ECJ had no grounds to conclude that the prohibition was unnecessary.<sup>62</sup> The ECJ found that the sole purpose of Article 4(7) was to provide that Member States do not have to allow imports into their own territory of food supplements containing ingredients not included on the "positive list."<sup>63</sup> With regards to Article 11(2), the ECJ found that its purpose was to

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57. *Id.* para. 115.

58. *Id.* paras. 123, 129.

59. *Alliance for Natural Health*, *supra* note 45, para. 54.

60. Food Supplements Directive, *supra* note 4. Under Article 11(1), Member States shall not prohibit or restrict trade in products that comply with the Food Supplements Directive.

61. *Alliance for Natural Health*, *supra* note 45, para. 60.

62. *Id.* para. 58.

63. *Id.* para. 57.

preserve national rules concerning nutrients other than vitamins and minerals until specific Community Rules were adopted.<sup>64</sup> Thus, the Community prohibition was not superfluous.

*B. Was the Food Supplements Directive Proportionate?*

The Claimants also argued that the “positive list” is unjustified and disproportionate because it goes beyond what is necessary to achieve the Community’s goal of protecting human health.<sup>65</sup> The Claimants asserted that the prohibition affects a large number of nutrients which are nonetheless suitable for a normal diet, are currently manufactured and marketed in certain Member States, and have not been shown to represent a risk to human health.<sup>66</sup> They also contended that adoption of a “negative list” that limits the prohibition to the substances included on that list would be a less restrictive alternative.<sup>67</sup>

To avoid exceeding the limits of what is appropriate and necessary when there is a choice between several appropriate measures, the least onerous one must be chosen by the legislature.<sup>68</sup> In his opinion on *Alliance for Natural Health*, the Advocate General clarified that the mere fact that the legislature might, in theory, have been able to attain a comparable level of protection for public health by use of less restrictive measures than those at issue, is insufficient to support the conclusion that the measure has infringed the principle of proportionality.<sup>69</sup> Rather, it must be an established fact that the alternative measure would, in the specific circumstances, be sufficient to attain the objective pursued by the contested measure.<sup>70</sup>

In *Alliance for Natural Health*, the ECJ found that by virtue of Article 7(1) of Regulation (EC) No 178/2002,<sup>71</sup> the Community is entitled to adopt the provisional risk management measures

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64. *Id.* para. 59.

65. *Id.* para. 62.

66. *Id.*

67. *Id.* para. 70.

68. Case C-157/96, *The Queen v. Min. of Agric., Fisheries and Food*, 1998 E.C.R. I-2211, para. 60.

69. Opinion of Advocate General, *supra* note 37.

70. Case C-491/01, *The Queen v. Sec’y of State for Health*, 2002 E.C.R. I-11453, para. 130.

71. Commission Regulation 178/2002, Laying Down the General Principles and Requirements of Food Law, Establishing the European Food Safety Authority and Laying Down Procedures in Matters of Food Safety, 2002 O.J. (L 183) 51, art. 7 (EC); *Alliance for Natural Health*, *supra* note 45, para. 69.

necessary to ensure a high level of health protection; further, it may do so while awaiting additional scientific information for a more comprehensive risk assessment.<sup>72</sup>

The ECJ also found that the alternative measure, use of a “negative list,” would not attain a comparable level of public health protection.<sup>73</sup> It would allow substances that were not on the “negative list,” by reason of their novelty for instance, to be placed on the market, even though they had not been subject to any scientific assessment of their safety for human consumption.<sup>74</sup> In addition, the ECJ upheld the standard set in *National Farmers’ Union*, maintaining that when there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent.<sup>75</sup>

Thus, the ECJ was correct in *Alliance for Natural Health* for doubting food supplements not on the “positive list,” that had not yet been evaluated by the Scientific Committee on Food (“SCF”), and lacked adequate and appropriate scientific data regarding their safety. The ECJ found also that it was reasonable for the authors of the Food Supplements Directive to reconcile the objective of the free flow of goods in the internal market with that of the protection of human health by limiting free movement to food supplements containing substances that have already been evaluated and found to be safe.<sup>76</sup> Furthermore, with no other measures having the same preventive effect on the protection of human health, the ECJ properly held that the “positive list” was not disproportionate.<sup>77</sup> Thus, the Food Supplements Directive did not infringe upon the proportionality principle.

## V. PUBLIC POLICY

The ECJ was correct not only for upholding the Food Supplements Directive under ECJ case law, but also for maintaining an approach that is in accord with sound public policy. This is shown by a quick review of food supplement regulation in the United States and current trends in the world today.

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72. *Alliance for Natural Health*, *supra* note 45, para. 69.

73. *Id.* para. 70.

74. *Id.*

75. *Id.* para. 68.

76. *Id.*

77. *Id.* para. 93.

### A. The DSHEA and Its Flaws

In the United States, food supplements are termed “dietary supplements”; they have been regulated as a separate category from food and medicine under the DSHEA since 1994.<sup>78</sup> The DSHEA was passed on the premise that safety problems with dietary supplements are rare and that the Federal Government should allow the public wider access to them.<sup>79</sup> The government also did not want to impose unreasonable regulatory barriers on such an important industry.<sup>80</sup> Thus, the DSHEA takes a much laxer approach to regulation than does the European Community’s Food Supplements Directive. Under the DSHEA, companies are not required to present any evidence to the Food and Drug Administration (“FDA”) that a dietary supplement is safe or effective prior to marketing; only a pre-market safety notification is needed for new dietary ingredients.<sup>81</sup> Thus, it is difficult for the FDA to regulate the safety of dietary supplements. The FDA is allowed to take action only after a supplement has been marketed and a public health concern has arisen.<sup>82</sup> Even then, the burden of proof falls on the FDA to show that the supplement is unsafe.<sup>83</sup> Because the DSHEA imposes no obligation on manufacturers of dietary supplements to inform the FDA when they learn of any adverse response to their products, the burden on the FDA is even more severe.<sup>84</sup>

Currently, there are many calls for the revision of the DSHEA based on its failure to effectively regulate dietary

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78. Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (codified as amended in scattered sections of 21 U.S.C. §§ 301-399 (2005)).

79. 21 U.S.C. § 321 (2000), notes 9, 14 (setting forth congressional findings that safety problems with dietary supplements are relatively rare and that almost fifty percent of Americans consume dietary supplements).

80. *Id.* § 321, note 12(A), (C) (setting forth congressional findings that the dietary supplement industry is an integral part of the U.S. economy because the estimated 600 dietary supplement manufacturers in the U.S. produce approximately 4,000 products, with total annual sales of such products reaching at least \$4 billion). In 2000, the U.S. dietary supplements market generated revenues of \$6.67 billion and that figure was estimated to reach \$21 billion by 2007. FoodNavigator.com, *US Sales Soar for Natural Dietary Supplements*, July 3, 2001, <http://www.foodnavigator.com/news/ng.asp?id=40273-us-sales-soar>.

81. Press Release, Food and Drug Admin., FDA Announces Major Initiatives for Dietary Supplements (Nov. 4, 2004), available at <http://www.fda.gov/bbs/topics/news/2004/NEW01130.html> [hereinafter FDA Press Release].

82. FDA Press Release, *supra* note 81.

83. 21 U.S.C. § 342(f) (2005).

84. FDA Press Release, *supra* note 81.

supplements.<sup>85</sup> In 1989, the dietary supplement L-tryptophan entered the U.S. market.<sup>86</sup> Within a few months, this caused an epidemic of a mysterious, disabling, and in some cases deadly autoimmune illness<sup>87</sup> called eosinophilia-myalgia syndrome (“EMS”),<sup>88</sup> which resulted in the death of thirty-seven people and the permanent disability of at least 1,500 others.<sup>89</sup> Under the DSHEA, the FDA is not allowed to step in and remove suspect supplements until after the damage has been done. In fact, as Dr. Richard Friedman, psychiatrist and director of the Psychopharmacology Clinic at New York Hospital-Cornell Medical Center, discovered, the FDA “couldn’t stop [someone] from selling hemlock tea until the bodies piled up.”<sup>90</sup>

### *B. How the Food Supplements Directive Avoids the Problems of the DSHEA*

The Food Supplements Directive aims to prevent episodes such as the preceding Tryptophan situation and would in fact have succeeded in doing so. The Food Supplements Directive requires all substances used in the manufacture of food supplements currently marketed to be evaluated by the SCF. Only the vitamins and minerals approved by the SCF and listed on the “positive list” can be used for the manufacture of food.<sup>91</sup> Because the Food Supplements Directive requires pre-market approval, food supplements must be safe for human health before being sold in the Community. Thus, the risks resulting from the intake of Tryptophan would have been discovered by the SCF before Tryptophan could have reached the market. Even Jim Murray,

85. Stephen M. Druker, *How The U.S. Food And Drug Administration Approved Genetically Engineered Foods Despite The Deaths One Had Caused And The Warnings Of Its Own Scientists About Their Unique Risks* (2001), <http://www.biointegrity.org/ext-summary.html>.

86. Druker, *supra* note 85.

87. Autoimmune diseases arise from an overactive immune response of the body against substances and tissues normally present in the body. In other words, the body attacks its own cells. THE NEW ENCYCLOPEDIA BRITANNICA 724 (15th ed. 1988).

88. ENCYCLOPEDIA & DICTIONARY OF MEDICINE, NURSING, & ALLIED HEALTH 607 (Marie T. O’Toole ed., 7th ed. 2003).

89. Druker, *supra* note 85.

90. Amber K. Spencer, Note, *The FDA Knows Best . . . Or Does It? First Amendment Protection of Health Claims on Dietary Supplements: Pearson v. Shalala*, 15 BYU J. PUB. L. 87, 113 (2000) (citing Gina Kolata, *The Unwholesome Tale of the Herb Market*, N.Y. TIMES, Apr. 21, 1996, at 1).

91. Food Supplements Directive, *supra* note 4, art. 4, at 53.

Director of the European Consumers' Organization (*Bureau Europeen des Unions de Consommateurs* "BEUC"), opined that the ECJ decision was "a clear victory for consumers and for the [European Union's] right to regulate on the safety of food products."<sup>92</sup>

### C. Current Trends

The Codex Commission ("Codex") is an international organization that was established by the United Nations' Food and Agriculture Organization and World Health Organization in 1962. With the creation of the World Trade Organization in 1994, the Codex was designated as the principal arbitral mechanism for resolving food trade disputes.<sup>93</sup> The Codex aims to set international standards and codes for foods.<sup>94</sup> The Codex met on November 4, 2003 to discuss a science-based framework to establishing upper limits on vitamin and mineral supplement dosage; it proposed that any finalized recommendations become the international standard.<sup>95</sup> Codex announced a positive outcome of that meeting, one that would "pave the way for the global sale and marketing of dietary supplements based on objective standards that will simultaneously preserve consumer safety and fair trade."<sup>96</sup>

In keeping with the trend on stricter regulations on food supplements, several countries, including Canada and New Zealand, have been working on passing laws similar to the Food Supplements Directive.<sup>97</sup> Canada, in particular, has decided to take an even stricter approach than the United States in regulating food supplements, which are referred to as natural health products ("NHPs") in Canada.<sup>98</sup> As of January 1, 2004, NHPs are treated as drugs and must meet all the manufacturing requirements of

92. Lister, *supra* note 2.

93. Press Release, Council For Responsible Nutrition, Codex Committee Backs Science-Based Safety Standards for Vitamin and Mineral Supplements – Breaks Eight-Year Stalemate (Nov. 4, 2003), <http://www.crnusa.org/shellnr110403.html> [hereinafter Codex].

94. Kathryn Alexander, *Natural Health Products: Guilty Until Proven Innocent?* (2004), <http://www.holistichealthtopics.com/HMG/codex2.html>.

95. *Id.*

96. Codex, *supra* note 93.

97. John C. Hammell, *Supplement Industry Under Massive Global Assault - What You Can Do To Fight Back*, June 21, 2003, [http://www.thenhf.com/eu\\_issues\\_03.html](http://www.thenhf.com/eu_issues_03.html).

98. Michael Penny & Conan McIntyre, *Canada and the United States: Crossborder Issues Relevant to the Dietary Supplements Industry*, UPDATE, Jan./Feb. 2005, at 25, available at <http://www.torys.com/publications/pdf/AR2005-2T.pdf>.

drugs.<sup>99</sup> A seller of a NHP must obtain a product license by the Natural Health Products Directorate (“NHPD”) before he may sell it.<sup>100</sup>

Even the United States has finally realized the need for stricter standards. It has recognized the need to update the decade-old DSHEA and has introduced the Major Initiatives for Dietary Supplements (“MIDS”).<sup>101</sup> In fact, “[w]ith the MIDS, the FDA intends to improve the “transparency, predictability, and consistency of its scientific evaluations and regulatory actions to protect consumers against unsafe dietary supplements making unauthorized, false, or misleading claims.”<sup>102</sup>

The MIDS contains three initiatives. The first is a regulatory strategy whereby the FDA will work collaboratively with other health agencies to improve the evidentiary base that the FDA uses to make safety and enforcement decisions about dietary supplements.<sup>103</sup> The second initiative is a public meeting designed to seek public comment on the type, quantity, and quality of evidence manufacturers should provide to the FDA in a new dietary ingredient notification.<sup>104</sup> The third initiative is a draft guidance document on the amount, type, and quality of evidence that a manufacturer should have to substantiate a structure function claim made under the Federal Food, Drug, and Cosmetic Act.<sup>105</sup>

## VI. CONCLUSION

Based on both ECJ case law and public policy, the ECJ reached the correct decision in upholding the European Community’s Food Supplements Directive in *Alliance for Natural Health*. Although many consumers believe that this regulation hampers their right of choice, the decision actually is a true win for consumer protection. The Food Supplements Directive picks up where the DSHEA had failed, preventing a predicament such as that in the United States where the FDA lacks the legislative

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99. *Id.* at 26.

100. Joel B. Taller, *Canada Issues Final Natural Health Product Regulations*, 60 HERBALGRAM 62 (2003), <http://www.herbalgram.org/herbalgram/articleview.asp?a=2599>.

101. FDA Press Release, *supra* note 81.

102. *Id.*

103. *Id.*

104. *Id.*

105. *Id.*



authority necessary to regulate supplements for the safety of the public. Understanding the problems that can result from a lack of harmonization among the Member States, the ECJ upheld the legislation, thereby bringing countries such as the United Kingdom with laxer regulations up to par with their fellow Member States. The Food Supplements Directive is also in line with Codex's aim of global harmonization of regulations on food supplements. Finally, the ECJ's decision reflects the desire to protect the Community from such tragedies as the EMS epidemic and to gain back the trust of the general public in all action by the Community in the field of consumer protection.

How Prime Minister Blair will address the current protests in the UK regarding the Food Supplements Directive is still to be seen. The ECJ, however, has shown that it stands strongly behind the Food Supplements Directive and will take the necessary actions to enforce it. The Court has already condemned the French Republic and ordered them to pay the costs for failing to comply with the Food Supplements Directive.<sup>106</sup> Thus, if the UK decides to follow in the French Republic's footsteps, they will likely face similar or even harsher consequences.

*Fiona LeCong\**

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106. Case C-57/05, *Comm'n of the European Cmty. v. French Republic*, available at <http://curia.europa.eu/jurisp/cgi-bin/form.pl?lang=en&Submit=Rechercher&alldocs=alldocs&docj=docj&docop=docop&docor=docor&docjo=docjo&numaff=C-57/05%20&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100>.

\* Juris Doctor Candidate, May 2007, Loyola Law School. The author would like to thank her fiancée, Vietnam Ly, and her parents, Hai and Trang Lecong, for their encouragement and support.