

# ANIMAL TESTING IN COSMETICS: RECENT DEVELOPMENTS IN THE EUROPEAN UNION AND THE UNITED STATES

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*Animal welfare has become a recent issue in the policy of the European Union. Since the creation of the European Economic Community (EEC) in 1957, the welfare of animals was only considered in relation to the proper functioning of the common market. Animals were seen as commodities whose interests were intertwined with agricultural and environmental policy. Over the years, the position has changed somewhat. Although a treaty basis exists for animal welfare, the protection of animals has not yet been recognized as an important policy area of its own, and thus worthy of legal protection. As a positive step in recognizing the unnecessary suffering of animals, the Cosmetics Directive will be the focus in the first part of this article. The amendments to the Cosmetics Directive to prohibit the testing of animals in cosmetics culminated in the case of France v. European Parliament and the Council of the European Union. The European Court of Justice and the Advocate General held against France and upheld the seventh amendment of the Cosmetics Directive. Similar measures were adopted in California, which will be discussed in the second half the article. Chapter 476, now a California statute, has banned animal testing except where there are no validated alternatives available. Chapter 476 is not without its critics, owing to its omission of standing for animal welfare groups. This has been the subject of both academic and judicial debate, and the analysis suggests that it will prove difficult for such groups to establish standing. Nevertheless, California is the first state to introduce legislation that prohibits the testing of cosmetics on animals, and this has prompted others to follow suit, with New York in the process of introducing similar legislation.*

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## I. INTRODUCTION

While animal welfare has made great strides since the seventeenth century, speaking of legal rights for animals has aroused much debate and consternation. This can be attributed to the fact that not all human beings have equal legal rights.<sup>1</sup> For many years, animals were denied rights because humans believed that animals' apparent lack of communication skills meant animals also lacked reason.<sup>2</sup> It was thought that animals acted only on instinct owing to their inferior mental and emotional intellect to humans.<sup>3</sup> As a result, "animals were thought to be simply machines, with their bodies interpreting environmental stimuli and translating them into behavior."<sup>4</sup> Since they lacked reason, Descartes argued that animals were not conscious of the experiences that surrounded them and, as a result, were incapable of suffer-

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<sup>1</sup> Tom Regan, *The Case for Animal Rights* 267 (U. Cal. Press 2004); see also Christopher D. Stone, *Should Trees Have Standing?—Toward Legal Rights for Natural Objects*, 45 S. Cal. L. Rev. 450, 450–51 (1972) (discussing how originally legal rights were granted to a narrow sector of society and, in some cases, were confined to those within a kinship).

<sup>2</sup> René Descartes formulated this idea in the seventeenth century. See Paola Cavalieri, *The Animal Debate: A Re-examination*, in *In Defense of Animals: The Second Wave* 58 (Peter Singer ed., Blackwell Publ. 2006).

<sup>3</sup> Susan E. Davis & Margo Demello, *Stories Rabbits Tell: A Natural and Cultural History of a Misunderstood Creature* 334 (Lantern Bks. 2003).

<sup>4</sup> *Id.* (adding that "[h]umans, on the other hand, were granted a vast array of learned behaviors, individual emotions and particular personalities that are shaped by a myriad of factors—including culture, the local environment, historical conditions, socioeconomic positions and, with the discovery of the modern science of genetics, inherited traits.").

ing.<sup>5</sup> Animals were viewed as inanimate objects, pieces of personal property that could not be ascribed rights.<sup>6</sup>

Moral rights, on the other hand, are more amenable to animals, with some people arguing that humans have duties towards animals.<sup>7</sup> In this situation, humans have an indirect duty towards animals, as the duty only arises in situations where it is in the interest of the human being.<sup>8</sup>

As Kant argued, “he who is cruel to animals becomes hard also in his dealings with men.”<sup>9</sup> Notwithstanding the philosophical debate, recent developments in both the European Union (EU)<sup>10</sup> and the United States (U.S.) suggest that animals are sentient beings and deserve the paternalistic protection of the law. This paper will begin with a discussion of Directive 76/768/EEC (Cosmetics Directive)<sup>11</sup> in the EU and will then discuss similar developments under California law and the

<sup>5</sup> Cavalieri, *supra* n. 2, at 58.

<sup>6</sup> Lauren Magnotti, Student Author, *Paving Open the Courthouse Door: Why Animals’ Interests Should Matter When Courts Grant Standing*, 80 St. John’s L. Rev. 455, 465 (2006).

<sup>7</sup> Cass R. Sunstein, *Standing for Animals*, 47 UCLA L. Rev. 1333, 1336 (2000); *id.* at 1336 n. 15.

<sup>8</sup> *Id.* at 1136 n. 15 (citing the opinion of Immanuel Kant).

<sup>9</sup> Immanuel Kant, *Lectures on Ethics* 240 (Louis Infield trans., Harper & Row 1978) (originally published in 1930).

<sup>10</sup> The EU currently has twenty-seven Member States; originally there were six: France, Germany, Italy, Belgium, Luxembourg, and the Netherlands. Jo Steiner, Lorna Woods & Christian Twigg-Flesner, *EC Law* 93–94 (8th ed., Oxford U. Press 2006). These States signed the European Coal and Steel Community (ECSC) Treaty in 1952. *Id.* In 1957, the six original Member States signed two more Community Treaties, the European Economic Community (EEC) Treaty and the European Atomic Energy Community. *Id.* The EEC was more economic in nature than the ECSC and had as its aim the creation of a common market between the six founding States. *Id.* The next important development was the Single European Act 1986. *Id.* at 5. Although called an Act, this Treaty intended to create an internal market, remove custom duties, and create a common customs tariff. The Treaty on European Union 1992 (also known as the Maastricht Treaty) created the three pillar structure. Europa, *European Treaties*, [http://europa.eu/abc/treaties/index\\_en.htm](http://europa.eu/abc/treaties/index_en.htm) (accessed Apr. 7, 2007). The three pillars are the Community Pillar, the Common Foreign and Security Policy Pillar, and Justice and Home Affairs Pillar. In 1997, the Treaty of Amsterdam was introduced and made changes to the Pillars. *Id.* In 2001, the Treaty of Nice was signed and this Treaty introduced changes into the Commission. *Id.* It extended qualified majority voting, broadened the functions of the Court of First Instance, and created a new body—Eurojust—to coordinate activities in the fight against transnational crime. More recently, the EU has consolidated all the earlier Treaties into one Treaty, the Constitutional Treaty, which has yet to be adopted by all the Member States. *Id.*

<sup>11</sup> Council Directive 76/768, 1976 O.J. (L 262) 169 (EEC) [hereinafter *Cosmetics Directive*] (available at <http://eur-lex.europa.eu/LexUriServ/site/en/consleg/1976/L/01976L0768-20060809-en.pdf>) (on file with *Animal L.*). A directive is a secondary piece of legislation that is binding on the Member States, but it is up to each Member State how it wishes to incorporate the directive into the national legal system. See Treaty Establishing the European Community, art. 249, Dec. 29, 2006, O.J. (C321E) 153 [hereinafter *EC Treaty*]; Steiner, Woods & Christian Twigg-Flesner, *supra* n. 10, at 3. The Official Journal (OJ) states when the directive is to be enacted, with a time frame of up to four years. If a Member State does not incorporate the directive within the proscribed

contentious issue of legal standing. The paper will conclude with a discussion of future developments.

## II. THE EUROPEAN UNION AND ANIMAL WELFARE

Animal welfare in the EU was recently called an “issue of very high importance.”<sup>12</sup> The European Commission (Commission)<sup>13</sup> recognizes animals as sentient beings and has a general aim of the avoidance of pain and suffering of animals.<sup>14</sup> The Commission obliges the owners or keepers of animals to respect minimal animal welfare requirements.<sup>15</sup> However, animals are still not recognized as having legal rights.

In the past, animal welfare received inadequate attention in the EU, and those protections that did exist were concerned with the proper functioning of the internal market.<sup>16</sup> The Treaty on European Union referred to animal welfare in the form of a Declaration.<sup>17</sup> The Treaty of Amsterdam (TA) then included a protocol on animal welfare.<sup>18</sup> An important feature of this protocol was the reference to ani-

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time, individuals may still be able to invoke the directive against their Member State in their national court under the principle of direct effect. *See generally id.* at 88–105.

<sup>12</sup> Markos Kyprianou, Speech, *Speech to the Animal Welfare Intergroup of the European Parliament* (Brussels, June 8, 2005) (available at [http://ec.europa.eu/food/animal/welfare/speech\\_05\\_335\\_en.pdf](http://ec.europa.eu/food/animal/welfare/speech_05_335_en.pdf)).

<sup>13</sup> EC Treaty art. 7 provides for institutions that are entrusted with carrying out the tasks of the Community, one of which is the Commission. The Commission embodies and upholds the general interest of the Union; it is often referred to as the “Guardian of the Treaties.” It formulates recommendations and opinions on matters dealt with in the Treaty, participates in the shaping of measures taken by the Council, and exercises powers conferred on it by the Council. *See* EC Treaty, *supra* n. 11, at arts. 211–19 (detailing the Commission and its duties).

<sup>14</sup> Eur. Commn., *Animal Welfare—Introduction*, [http://europa.eu.int/comm/food/animal/welfare/index\\_en.htm](http://europa.eu.int/comm/food/animal/welfare/index_en.htm) (accessed Feb. 9, 2007).

<sup>15</sup> *Id.*

<sup>16</sup> For examples, see EC Treaty, *supra* n. 11, at art. 37 (governing agriculture); EC Treaty art. 95 (governing the internal market); EC Treaty, *supra* n. 11, at art. 175 (governing environmental issues).

<sup>17</sup> Treaty on European Union, *Declaration on the Protection of Animals*, July 29, 1992, 1992 O.J. (C 191) (available at <http://eur-lex.europa.eu/en/treaties/dat/11992M/htm/11992M.html#0103000044>); *see* Tara Camm & David Bowles, *Animal Welfare and the Treaty of Rome—A Legal Analysis of the Protocol on Animal Welfare and Welfare Standards in the European Union*, 12 J. Env'tl. L. 197, 198 (2000) (stating that while the Declaration called for the European Parliament, the Council and the Commission, and the Member States to regard animal welfare, it had little legal effect).

<sup>18</sup> *See* Treaty of Amsterdam amending the Treaty on the European Union, *Protocol on Protection and Welfare of Animals*, Oct. 11, 1997, 1997 O.J. (C 340) 110 [hereinafter TA Protocol] (stating that “[i]n formulating and implementing the Community’s agricultural, transport, internal market and research policies, the Community and the Member States shall pay full regard to the welfare requirements of animals, while respecting the legislative or administrative provisions and customs of the Member States relating in particular to religious rites, cultural traditions and regional heritage”) (available at <http://www.europarl.europa.eu/topics/treaty/pdf/amst-en.pdf>). The Treaty of Amsterdam introduced “for the first time legal obligations enshrined within the EC Treaty to have regard to animal welfare in key areas of European law and policy.” Camm &

mals as “sentient beings.”<sup>19</sup> However, the TA did not provide any legal basis for the introduction of legislation in relation to animal welfare.<sup>20</sup> The protection of animals has been intertwined with other policy issues such as agriculture or the environment.<sup>21</sup> Consequently, animal welfare has yet to be recognized as an important policy area of its own, and thus worthy of legal protection. The Treaty Establishing a Constitution for Europe attempts to give animal welfare a more tangible legal basis.<sup>22</sup> Article III-121 is very similar to the protocol in that it recognizes animals as sentient beings, but its effect is weakened by the exception given to Member States on the basis of religious rites and cultural traditions.<sup>23</sup>

### III. THE EUROPEAN UNION AND ANIMAL TESTING

In 1976, the European Community (EC) introduced the Cosmetics Directive to approximate the laws of the Member States in relation to cosmetic products.<sup>24</sup> The Cosmetics Directive aims to determine “at Community level the regulations which must be observed as regards the composition, labeling and packaging of cosmetic products . . . .”<sup>25</sup> The EC introduced the Cosmetics Directive after much deliberation between experts from all the Member States.<sup>26</sup>

The aim was two-fold: to guarantee the safety of cosmetic products for human use and thus benefit the consumer, and to encourage commercial exchange between the Member States, thus eliminating barriers to trade.<sup>27</sup> At the time of the Cosmetics Directive, no provisions existed relating to animal welfare.

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Bowles, *supra* n. 17, at 197. “The protocol also leaves Member States free to introduce national legislation relating to issues such as animal welfare in circuses, equine competitions, greyhound racing, hunting with hounds, and bullfighting.” Eurogroup for Animals, *The Treaty and Animal Welfare*, [http://eurogroupforanimals.org/legislation/legislation\\_more1.htm?#art1](http://eurogroupforanimals.org/legislation/legislation_more1.htm?#art1) (accessed Feb. 10, 2007).

<sup>19</sup> TA Protocol, *supra* n. 18. “Sentient beings” refers to animals being viewed as animate and living creatures as opposed to goods.

<sup>20</sup> *Id.*

<sup>21</sup> See EC Treaty, *supra* n. 1.

<sup>22</sup> Treaty Establishing a Constitution for Europe, *Part III: The Policies and Functioning of the Union, Title I Provisions of General Application*, art. III-121, Oct. 29, 2004, 2004 O.J. (C 310) 55, 55–56 [hereinafter Constitutional Treaty] (available at [http://eurlex.europa.eu/LexUriServ/site/en/oj/2004/c\\_310/c\\_31020041216en00550185.pdf](http://eurlex.europa.eu/LexUriServ/site/en/oj/2004/c_310/c_31020041216en00550185.pdf)).

<sup>23</sup> *Id.* at 56.

<sup>24</sup> Cosmetics Directive, 1976 O.J. (L 262) at 169.

<sup>25</sup> *Id.* Britain, Austria, and the Netherlands have already prohibited animal testing in cosmetics. Humane Socy. U.S., *French Government Challenges EU Cosmetics Directive*, [http://www.hsus.org/animals\\_in\\_research/animals\\_in\\_research\\_news/french\\_government\\_challenges\\_eu\\_cosmetics\\_directive.html](http://www.hsus.org/animals_in_research/animals_in_research_news/french_government_challenges_eu_cosmetics_directive.html) (accessed Apr. 7, 2007).

<sup>26</sup> Commn. Eur. Communities, *The Rules Governing Cosmetics Products in the European Union, Volume I: Cosmetics Legislation—Cosmetic Products* iii (Off. for Official Publications of the European Communities 1999) (available at [http://leffingwell.com/cosmetics/vol\\_1en.pdf](http://leffingwell.com/cosmetics/vol_1en.pdf)).

<sup>27</sup> Cosmetics Directive, 1976 O.J. (L 262) at 169.

In 1993, Directive 93/35/EEC incorporated a new Article 4(1)(i) into the Cosmetics Directive which provided that Member States, in order to comply with the requirements of the Directive, were obliged to prohibit the marketing of cosmetic products containing ingredients that had been tested on animals.<sup>28</sup> The January 1, 1998 deadline was postponed to June 30, 2000—and then to June 30, 2002—as an insufficient number of alternative testing methods had been scientifically validated.<sup>29</sup>

In April 2000, the Commission proposed a seventh amendment to the Cosmetics Directive.<sup>30</sup> The Commission proposed, *inter alia*, to introduce a testing ban on animals for finished cosmetic goods within the Member States.<sup>31</sup> It also proposed that the marketing ban—a prohibition on the sale and marketing of cosmetic products that have been tested on animals—contained in the Cosmetics Directive be removed.<sup>32</sup>

In February 2002, the Council<sup>33</sup> adopted a Common Position on the proposed amendment and reinstated the marketing ban on cosmetic products where the final product or its ingredients have been subject to animal testing.<sup>34</sup> However, the Council made the implementation of the marketing ban subject to the existence of alternative testing methods accepted within the framework of the Organization for Economic Co-Operation and Development (OECD) toxicity test guide-

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<sup>28</sup> Council Directive 93/35, 1993 O.J. (L 151) 32, 33 (EEC).

<sup>29</sup> Commn. Directive 97/18, art. 1, 1997 O.J. (L 114) 43, 44 (EC) (postponing the 1998 deadline to June 30, 2000); Commn. Directive 2000/41, art. 1, 2000 O.J. (L 145) 25, 25 (EC) (the second postponement to June 30, 2002).

<sup>30</sup> Commn. Eur. Communities, *Proposal for a Directive of the European Parliament and of the Council Amending for the Seventh Time Council Directive 76/768/EEC on the Approximation of the Laws of the Member States Relating to Cosmetic Products*, at 2, COM (2000) 189 final (Apr. 5, 2000) [hereinafter Commn. Eur. Communities, COM (2000) 189] (on file with *Animal L.*).

<sup>31</sup> *Id.* Article 1(3)(a) defines a “finished cosmetic product” as the cosmetic product in its final formulation, as placed on the market and made available for sale to the final consumer, or its prototype. Council Directive 2003/15, *Amending Council Directive 76/768/EEC*, 2003 O.J. (L66) 26 (EC) [hereinafter *CDA*, which stands for Cosmetics Directive Amendment] (available at [http://ec.europa.eu/enterprise/cosmetics/doc/200315/200315\\_en.pdf](http://ec.europa.eu/enterprise/cosmetics/doc/200315/200315_en.pdf)) (on file with *Animal L.*). “Prototype” is defined as a first model or design that has not been produced in batches, and from which the finished cosmetic product is copied or finally developed. *Id.* at art. 1(3)(b), 2003 O.J. (L66) at 29.

<sup>32</sup> Commn. Eur. Communities, COM (2000) 189 at 2.

<sup>33</sup> The Council consists of one representative from each Member State. Unlike the Commission, the Council does not have fixed membership. The “basic” Council consists of the Foreign Ministers of the Member States, who discuss not only foreign affairs, but also issues of general concern. However, if a more specialized area is under discussion, the Council will consist of ministers from that policy area, for example the ministers for Agriculture and Trade. The members must be “at ministerial level, [authorized] to commit the government of that Member State.” *See generally* EC Treaty, *supra* n. 11, at art. 203.

<sup>34</sup> Council Common Position (EC) No. 29/2002 of 14 February 2002, art. 1, 2002 O.J. (C 113) 109, 110 (on file with *Animal L.*).

lines and those adopted at the EC level.<sup>35</sup> The Common Position did not include deadlines for the implementation of the marketing ban.

In June 2002, the Parliament<sup>36</sup> adopted a position on the Council's Common Position.<sup>37</sup> It suggested a number of amendments, including the introduction of a marketing ban when alternative methods of testing became available.<sup>38</sup> The Parliament also suggested a definitive date after which no cosmetic products could be marketed if tested on animals, irrespective of there being validated alternatives at that time.<sup>39</sup> In July 2002, the Commission adopted an Opinion on the Parliament's amendments to the Council's Common Position.<sup>40</sup> In its Opinion, the Commission rejected the Parliament's proposal to reintroduce the marketing ban.<sup>41</sup> A conciliation committee of the Parliament and the Council was convened in October and November 2002.<sup>42</sup> The Council and the Parliament consequently approved the joint text.<sup>43</sup> This text represents a compromise between the respective positions of the Parliament and the Council. In 2003, the Parliament introduced an amendment to the Cosmetics Directive.<sup>44</sup>

Amending Council Directive 2003/15/EC (CDA) amends the Cosmetics Directive to add Article 4a, which prohibits the sale of any new or existing product that has been tested on animals in disregard of

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<sup>35</sup> *Id.*

<sup>36</sup> In 1957, under the EEC (which was changed to the European Community Treaty (EC) under the Treaty on European Union in 1993), the Parliament was termed an Assembly with a supervisory and advisory role. The early treaties provided this "Assembly" with very few powers. Over the years, the role of the Assembly changed, and in 1986, under the Single European Act, its name was changed to the Parliament. The Parliament is not a legislature in the commonly accepted sense of that term, as it has no power of initiation (legislation) and no right to raise taxes. However, in recent years, it has played an increasingly powerful role in the decision making process. *See* EC Treaty arts. 189–201.

<sup>37</sup> Eur. Parl. Comm. on the Env., Pub. Health & Consumer Policy, *Recommendation for a Second Reading on the Council Common Position for Adopting a European Parliament and Council Directive Amending Council Directive 76/768/EEC*, Doc. (A5-0180) (2002) (available at <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+REPORT+A5-2002-0180+0+DOC+PDF+V0//EN&language=EN>).

<sup>38</sup> *Id.* at 6–7.

<sup>39</sup> *Id.* at 7.

<sup>40</sup> Commn. Eur. Communities, *Opinion of the Commission on the European Parliament's Amendments to the Council's Common Position*, COM (2002) 435 final (July 26, 2002) [hereinafter Commn. Eur. Communities, COM (2002) 435] (on file with *Animal L.*).

<sup>41</sup> *Id.* at 4.

<sup>42</sup> Eur. Parl. Conciliation Comm., *Report on the Joint Text Approved by the Conciliation Committee for a European Parliament and Council Directive of the European Parliament and of the Council Amending Council Directive 76/768/EEC*, Doc. (A5-0001) ¶ 5, 6 (2003) [hereinafter Eur. Parl. Conciliation Comm., *Conciliation Report*, Doc. (A5-0001)] (available at <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+REPORT+A5-2003-0001+0+DOC+PDF+V0//EN&language=EN>) (on file with *Animal L.*).

<sup>43</sup> *Id.* at 4.

<sup>44</sup> CDA, 2003 O.J. (L66) at 26.

existing alternative testing methods.<sup>45</sup> Article 4a(1) prohibits the following:

- (a) the marketing of cosmetic products where the final formulation, in order to meet the requirements of this Directive, has been the subject of animal testing using a method other than an alternative method after such alternative method has been validated and adopted at Community level with due regard to the development of validation within the OECD;
- (b) the marketing of cosmetic products containing ingredients or combinations of ingredients which, in order to meet the requirements of this Directive, have been the subject of animal testing using a method other than an alternative method after such alternative method has been validated and adopted at Community level with due regard to the development of validation within the OECD;<sup>46</sup>
- (c) the performance on their territory of animal testing of finished cosmetic products in order to meet the requirements of this Directive;
- (d) the performance on their territory of animal testing of ingredients or combinations of ingredients in order to meet the requirements of this Directive, no later than the date on which such tests are required to be replaced by one or more validated alternative methods.<sup>47</sup>

Article 4a(1) will come into force in 2009; thus Member States have until then to implement it.<sup>48</sup> This will result in a near total ban on the marketing and testing of animals for cosmetic products.<sup>49</sup> Under Article 4a(2), the Commission was given the task of establishing timetables for the implementation of the provisions under Articles 4a(1)(a), (b), and (d).<sup>50</sup> Article 4a(1)(c), concerning the prohibition of animal testing for finished cosmetics, had to be implemented by September 11, 2004,<sup>51</sup> while Articles 4a(1)(a), (b), and (d) are to be implemented by March 2009.<sup>52</sup> This marketing ban was to be incorporated into national legislation by Member States by September 2004. Imple-

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<sup>45</sup> *Id.* at 28.

<sup>46</sup> *Id.* (Article 4a(2) establishes that the maximum time limit for this, and specifically for tests of repeated-dose toxicity, reproductive toxicity, and toxicokinetics where there are no alternatives under consideration, is ten years.).

<sup>47</sup> *Id.*

<sup>48</sup> *Id.* at 28.

<sup>49</sup> *Id.* at 28–29.

<sup>50</sup> *CDA*, 2003 O.J. (L 66) at 28. These timetables were to be established following consultation with various groups, including the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFD) and the European Centre for the Validation of Alternative Methods (ECVAM). *Id.* Due regard was also to be had for the Organisation for Economic Cooperation and Development (OECD) guidelines in relation to the development of validation. *Id.* “ECVAM was created by a Communication from the Commission to the Council and the Parliament in October, 1991” in response to a requirement in Directive 86/609/EEC. *See ECVAM, About ECVAM: Reason for ECVAM*, <http://ecvam.jrc.it/index.htm> (accessed Feb. 13, 2007) (explaining that Directive 86/609/EEC requires the Commission and the Member States to actively support the development, validation, and acceptance of methods which could reduce, refine, or replace the use of laboratory animals).

<sup>51</sup> *CDA*, 2003 O.J. (L66) at 28.

<sup>52</sup> *Id.*



mentation was postponed,<sup>53</sup> because the Commission and the Council, while advocating a ban on animal testing if validated alternatives exist, objected to a marketing ban on cosmetic goods.<sup>54</sup> Cosmetic product tests regarding repeated dose toxicity, reproductive toxicity, and toxicokinetics, where there are not yet validated alternatives, must be banned by 2013.<sup>55</sup> However, this deadline is extendable if non-animal alternatives are still unavailable by 2013.<sup>56</sup>

France objected to the CDA and issued annulment proceedings against the Council and the Parliament in *French Republic v. European Parliament and Council of the European Union*.<sup>57</sup> In May 2005, the European Court of Justice (ECJ) handed down judgment in the case and dismissed the action.<sup>58</sup>

The main source of contention for France was Article 1(2) of the CDA, which introduces a new Article 4a into the original Cosmetics Directive.<sup>59</sup> Article 4a(1) will prohibit the testing of cosmetics on animals and the marketing of such products in the EU.<sup>60</sup> The near total ban is to come into force by March 2009, but if no valid alternatives exist by 2009, a total prohibition must be implemented by 2013.<sup>61</sup> France objected to the contested provision, arguing that it infringed upon the principles of legal certainty, proportionality, precaution, non-discrimination, and the freedom to pursue a professional activity.<sup>62</sup> On

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<sup>53</sup> Humane Socy. U.S., *French Government Challenges EU Cosmetics Directive*, [http://www.hsus.org/animals\\_in\\_research/animals\\_in\\_research\\_news/french\\_government\\_challenges\\_eu\\_cosmetics\\_directive.html](http://www.hsus.org/animals_in_research/animals_in_research_news/french_government_challenges_eu_cosmetics_directive.html) (Jan. 24, 2005).

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

<sup>55</sup> CDA, 2003 O.J. (L66) at 28.

<sup>56</sup> *Id.* at art. 1(2.2) at 28–29.

<sup>57</sup> Case C-244/03, *French Republic v. European Parliament and the Council of the European Union*, 2003 O.J. (C 171) 20. EC Treaty art. 230 provides that Member States, the Council, the Commission, and the Parliament may request annulment of a Community provision. Annulment proceedings also give the Court of Justice the opportunity to examine the legality of acts adopted by the Community institutions. Council Directive 325/33, art. 230, 2002 O.J. (C 325) 126 (EC). Under EC Treaty art. 231, if the proceedings are found to be justified, the disputed act may be declared null and void. *Id.* at 127. France was the only Member State to publicly object to the ban on animal testing and marketing of animal tested cosmetics products. Humane Socy. U.S., *supra* n. 53.

<sup>58</sup> Case C-244/03, *Judgment of the Court in French Republic v. European Parliament and Council of the European Union*, 2005 E.C.R. I-04021 [hereinafter Case C-244/03, *Judgment*, 2005 E.C.R. I-04021] (on file with *Animal L.*).

<sup>59</sup> CDA, 2003 O.J. (L66) at 28.

<sup>60</sup> *Id.*

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

<sup>62</sup> Case C-244/03, *Judgment*, 2005 E.C.R. I-04021 at ¶ 7; see also Azalea P. Rosholt, *The Seventh Amendment Directive—An Unnecessary Measure to a Necessary End—Possible Legal Challenges to Directive 2003/15/EC of the European Parliament and of the Council Amending Council Directive 76/768/EEC under European Union Law*, 60 Food & Drug L.J. 421, 431–33 (2005) (making a number of interesting arguments that Article 4a is legally deficient).

May 24, 2005, the Grand Chamber of the ECJ held that the partial annulment sought was impossible, and the action was dismissed.<sup>63</sup>

#### IV. FRANCE V. THE COMMISSION AND PARLIAMENT

France argued that Article 1(2) of the CDA, which introduces Article 4a into the Cosmetics Directive, should be annulled and severed from the other provisions of the CDA, which would continue to have legal effect.<sup>64</sup> The French government believed that Article 1(2) of the CDA infringed the principle of legal certainty.<sup>65</sup> France's argument centered on the EC legislature's failure to define clearly and precisely the scope of Article 4a, as well as the use of the expression "in order to meet the requirements of this Directive," which the French Government felt would result in the CDA being transposed in divergent ways in the national legal systems of the Member States.<sup>66</sup>

France also raised the argument that legal certainty is even more important when it places obligations on individuals.<sup>67</sup> Due to the imprecise nature of Article 4a, France argued that the lack of clarity would render cosmetics companies incapable of determining what circumstances and legal relationships fell within the scope of that article.<sup>68</sup> Given that cosmetic companies need to maintain their position on the international markets and avoid falling behind in developing innovative products, France contended that the cosmetic industry in Europe should be able to determine exactly what is intended by the CDA.<sup>69</sup> The French government alluded to its position as EU leader in the cosmetic sector, with half of its turnover being earned from exportation.<sup>70</sup> France submitted that legal certainty was necessary to maintain the competitive position of the EU cosmetic industry, as the number of substances usable in the cosmetics industry would be greatly diminished if the contested provision were not severed from the rest of the Directive.<sup>71</sup>

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<sup>63</sup> Case C-244/03, *Judgment*, 2005 E.C.R. I-04021.

<sup>64</sup> *Id.* at ¶ 1.

<sup>65</sup> *Id.* at ¶ 7.

<sup>66</sup> 2005 Op. Adv. Gen. Geelhoed E.C.R. I-04021 ¶ 32 (2005) (on file with *Animal L.*).

<sup>67</sup> *Id.*

<sup>68</sup> *Id.*

<sup>69</sup> *Id.* at ¶ 33.

<sup>70</sup> *Id.* at ¶ 33. France is home to L'Oreal, Clarence, and Clinique. L'Oreal owns, among others, the following brands: Garnier, Maybelline NY, Kerastase, Lancôme, Bioterm, Helena Rubenstein, Kiehl's, Giorgio Armani, Ralph Lauren, shu uemura, Cacheral, Viktor & Rolf, Vichy, La Roche-Posay, and innéov. China, Korea, Japan, and to some extent the United States, are main importers of EU cosmetics, and these countries require that cosmetics are safe for human use before market authorization will be granted.

<sup>71</sup> *Id.* at ¶ 33.

*A. Partial Annulment*

The French government also proposed a partial annulment of Article 4a insofar as it infringed on the freedom to pursue a professional activity.<sup>72</sup> France reasoned that such interference was excessive, intolerable, and contrary to the principle of proportionality.<sup>73</sup> France also argued that the intended aim of the CDA, improving animal welfare, was extremely small; while the implementation of Article 4a would, in France's view, present a significant risk to human health due to a dearth of alternative methods of testing.<sup>74</sup> France claimed that the principle of precaution had been infringed, as the legislature had allowed human health to be exposed to unacceptable risks.<sup>75</sup> Finally, France argued that the contested Article infringed on the principle of non-discrimination because it has the potential to upset the level of equality among companies in the cosmetic industry and gave no objective reason.<sup>76</sup> For example, France contended that companies active purely in the cosmetics sector could be treated differently from companies active in other industries, as the latter could use ingredients tested on animals for other purposes.<sup>77</sup>

France looked to Article 4a(2.4), which allows a Member State to request the Commission to grant an exception from Article 4a(1) in "exceptional circumstances where serious concerns arise as regards the safety of an existing cosmetic ingredient . . . ."<sup>78</sup> The Commission, after consultation with the Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers (SCCNFP), may grant an exception in the form of a reasoned decision.<sup>79</sup> France argued that the exception was so strict as to render it ineffective.<sup>80</sup>

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<sup>72</sup> 2005 Op. Adv. Gen. Geelhoed E.C.R. I-04021 at ¶ 34.

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

<sup>74</sup> *Id.* at ¶¶ 35, 37 (estimating that only 0.3% of animal tests are carried out for cosmetic products); see also Simon Pitman, *France Loses Appeal against Testing ban*, <http://www.cosmeticsdesign.com/news/news-ng.asp?n=60242-france-loses-appeal> (May 25, 2005) (noting eleven million animal experiments in the EU per annum, with cosmetics testing accounting for 0.25%); compare Naturewatch, *Compassionate Shopping*, [http://www.naturewatch.org/shoppingguide/loreal\\_response.asp](http://www.naturewatch.org/shoppingguide/loreal_response.asp) (accessed Feb. 14, 2007) (L'Oreal contends that there are no alternatives for toxicity and skin irritation tests) with The Interagency Coordinating Comm. on the Validation of Alt. Methods (ICCVAM) & The Natl. Toxicology Program Interagency Ctr. for the Evaluation of Alt. Toxicology Methods (NICEATM), *infra* n. 151 (discussing alternative toxicity and skin irritation tests).

<sup>75</sup> 2005 Op. Adv. Gen. Geelhoed E.C.R. I-04021 at ¶ 37.

<sup>76</sup> *Id.* at ¶ 38.

<sup>77</sup> *Id.*

<sup>78</sup> *Id.* at ¶ 17.

<sup>79</sup> *Id.* The Commission authorizes an exception under the terms of procedure referred to in CDA, art. 10(2), 2003 O.J. (L 66) at 26–35.

<sup>80</sup> 2005 Op. Adv. Gen. Geelhoed E.C.R. I-04021 at ¶ 36.

### B. GATT/WTO Considerations

France argued that the EU provisions on animal testing and the marketing ban were incompatible with World Trade Organization (WTO) law on the freedom to pursue a profession.<sup>81</sup> France contended that the protection of animals did not constitute an EC objective of general interest that warranted a restriction of this freedom.<sup>82</sup> As WTO rules prohibit the discrimination against foreign products,<sup>83</sup> France argued that the marketing ban would breach this provision.<sup>84</sup> In the words of Advocate General (AG) Geelhoed, France argued that the marketing ban amounted “to an economic embargo to force other members to adopt essentially the same global regulations in order to achieve an objective defined on Community territory.”<sup>85</sup>

Article XX of the General Agreement on Tariffs and Trade (GATT) allows an exception to free trade.<sup>86</sup> France acknowledged the aim of Article XX (the protection of the life and health of animals), but contended that less onerous measures would have obtained the same objective without breaching WTO rules.<sup>87</sup> However, in 2000, Article XX was used in the U.S. to ban the importation and sale of dog and cat fur products.<sup>88</sup> In light of this decision, France’s argument in relation to Article XX was weakened.

### C. The Opinion of the Advocate General Geelhoed

Advocate General Geelhoed delivered his Opinion on March 17, 2005.<sup>89</sup> The AG looked at the legislative background of the Cosmetics

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<sup>81</sup> See *id.* at ¶ 34 (describing France’s arguments regarding freedom to pursue a profession); *id.* at ¶ 43 (stating “[o]n the basis of these arguments, the French Government concludes [the Article 4a marketing ban] is incompatible with WTO law”).

<sup>82</sup> *Id.* at ¶ 34.

<sup>83</sup> *General Agreement on Tariffs and Trade*, art. III, § 4 (Oct. 30, 1947), 61 Stat. A-11 [hereinafter *GATT*] (“The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less [favorable] than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use.”) (available at [http://www.wto.org/English/docs\\_e/legal\\_e/gatt47\\_01\\_e.htm](http://www.wto.org/English/docs_e/legal_e/gatt47_01_e.htm)).

<sup>84</sup> 2005 Op. Adv. Gen. Geelhoed E.C.R. I-04021 at ¶ 41.

<sup>85</sup> *Id.* at ¶ 42.

<sup>86</sup> *GATT*, art. XX (“Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures . . . necessary to protect human, animal or plant life or health.”).

<sup>87</sup> 2005 Op. Adv. Gen. Geelhoed E.C.R. I-04021 at ¶ 42.

<sup>88</sup> 19 U.S.C. § 1308 (2000). The issue of dog and cat fur being used in clothing imported from Third Countries is discussed in the Speech by Markos Kyprianou. Kyprianou, *supra* n. 12.

<sup>89</sup> 2005 Op. Adv. Gen. Geelhoed E.C.R. I-04021. There are two courts in the Community court system: the European Court of Justice (ECJ) and the Court of First Instance (CFI). The ECJ has eight Advocate Generals (AG). Each AG gives a lengthy opinion on

Directive,<sup>90</sup> the contested Article 4a provision,<sup>91</sup> the arguments raised by the French government,<sup>92</sup> and the arguments of the Council<sup>93</sup> and the Parliament.<sup>94</sup> The AG looked at the issue of partial annulment of Article 1(2) of the CDA.<sup>95</sup> In his examination of the case law, the AG found that the contested provision was not severable from the rest of the CDA, and thus declared the action inadmissible.<sup>96</sup> The AG went on to examine the substance of the parties' arguments on the hypothesis that the ECJ might find the contested provision severable.<sup>97</sup>

On the issue of legal certainty, the AG rejected the arguments made by France.<sup>98</sup> He reasoned that the prohibition on animal testing applied equally to tests carried out for the purposes of complying with other legislation, in that substances that had been the subject of such tests could not be used in cosmetic products.<sup>99</sup> Such an interpretation "seem[ed] necessary for the *effet utile* of the Directive and is consistent with the intention expressed in the preparatory documents leading up to its adoption."<sup>100</sup> From the AG's interpretation, the contested provision applied to the carrying out of animal testing of cosmetic products or ingredients on a Member State's territory, irrespective of whether the products were intended for export.<sup>101</sup> The AG drew on the wording of Article 1(7) of the CDA to support this conclusion.<sup>102</sup> In the AG's opinion, the contested provision did not lack legal certainty, and in the event of an undertaking questioning its interpretation, a case could be brought before the national court, which could in turn refer the matter to the ECJ under Article 234 of the EC Treaty.<sup>103</sup> By rejecting the proportionality argument, the AG found that the contested provision "represent[ed] a careful and considered balance by the Community legislature between the interests at stake."<sup>104</sup> In his discussion on the principle of precaution, the AG referred to *Arnold André GmbH & Co.*

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all aspects of the case. The opinion will usually conclude with a recommendation. The AG does not decide the case, nor is his/her reasoning binding on the court, but it carries significant weight. See generally EC Treaty, *supra* n. 11, at arts. 220–45.

<sup>90</sup> 2005 Op. Adv. Gen. Geelhoed E.C.R. I-04021 at ¶¶ 2–10.

<sup>91</sup> *Id.* at ¶¶ 11–19.

<sup>92</sup> *Id.* at ¶¶ 29–43.

<sup>93</sup> *Id.* at ¶¶ 44–51.

<sup>94</sup> *Id.* at ¶¶ 52–58.

<sup>95</sup> *Id.* at ¶¶ 59–70.

<sup>96</sup> 2005 Op. Adv. Gen. Geelhoed E.C.R. I-04021 at ¶¶ 70, 87, 105, 109–10, 113, 124–25.

<sup>97</sup> *Id.* at ¶ 70.

<sup>98</sup> *Id.* at ¶ 83.

<sup>99</sup> *Id.* at ¶ 84.

<sup>100</sup> *Id.* at ¶ 84.

<sup>101</sup> *Id.* at ¶ 85.

<sup>102</sup> 2005 Op. Adv. Gen. Geelhoed E.C.R. I-04021 at ¶ 84.

<sup>103</sup> *Id.* at ¶ 87. EC Treaty Article 234 is a preliminary reference procedure. EC Treaty, *supra* n. 11, at art. 234.

<sup>104</sup> *Id.* at ¶ 105.

*KG v. Landrat des Kreises Herford*,<sup>105</sup> where the ECJ defined the principle:

When it is impossible to determine with certainty the existence or scope of an alleged risk due to the insufficient, inconclusive, or imprecise nature of results or studies, but the probability of real damage to public health persists in the case that the risk would materialize, the principle of precaution justifies the adoption of the restrictive manner.<sup>106</sup>

When dismissing France's argument, the AG made the point that in order to invoke the principle of precaution, a party must prove that the alleged risk is more than hypothetical.<sup>107</sup> Since the French government had not adduced any evidence of "any more than a hypothetical" risk to public health, its argument on this basis was dismissed.<sup>108</sup> Because the AG had already found that the contested provision did not lack legal certainty, the French government's arguments on non-discrimination were also rejected, as these arguments were based on the hypothesis that Article 1(2) lacked legal certainty.<sup>109</sup>

On the issue of whether Article 4a restricts the pursuit of a professional activity, the AG reiterated the comments made by the ECJ in the case of *Metronome Musik GmbH v. Musik Point Hokamp GmbH*.<sup>110</sup> In that case, the ECJ recognized the right to pursue a professional activity, but added that it was not absolute and could be restricted, provided that the restriction was not disproportionate to the aim it sought to achieve.<sup>111</sup> In using the same analogy, the AG found that the restriction did not represent a disproportionate interference with the freedom to pursue a profession.<sup>112</sup> In addressing the relevance of WTO law, the AG recognized two situations in which the ECJ may review measures of the EC institutions against the WTO Agreement and its annexes: "namely, where the Community intended to implement a particular obligation assumed in the context of the WTO, or where the Community measure refers expressly to the precise provisions of the WTO agreements."<sup>113</sup> Because neither of these situations existed, the AG determined that Article 4a cannot be reviewed in light of the WTO Agreement and its annexes.<sup>114</sup>

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<sup>105</sup> Case C-434/02, *Arnold André GmbH & Co. KG v. Landrat des Kreises Herford*, 2004 E.C.R. I-11825.

<sup>106</sup> 2005 Op. Adv. Gen. Geelhoed E.C.R. I-04021 at ¶ 106 (citing Case C-434/02, 2004 E.C.R. I-11825).

<sup>107</sup> *Id.* at ¶ 107.

<sup>108</sup> *Id.* at ¶ 109.

<sup>109</sup> *Id.* at ¶ 110.

<sup>110</sup> Case C-200/96, *Metronome Musik GmbH v. Music Point Hokamp GmbH*, 1998 E.C.R. I-01953 (on file with *Animal L.*).

<sup>111</sup> *Id.* at ¶ 21.

<sup>112</sup> 2005 Op. Adv. Gen. Geelhoed E.C.R. I-04021 at ¶ 113.

<sup>113</sup> *Id.* at ¶ 115.

<sup>114</sup> *Id.*

The AG then turned to the arguments raised by France in regard to Article III.4 of GATT.<sup>115</sup> France argued that Article 4a amounted to a “marketing prohibition of all animal tested cosmetic products that use a method other than an alternative method after such alternative method has been validated and adopted at Community level.”<sup>116</sup> In France’s view, such a provision constituted less favorable treatment within the meaning of Article III.4 of GATT,<sup>117</sup> as importers into the EC are required to “have their alternative method validated at Community level.”<sup>118</sup> The AG rejected this argument and contended that:

While it is clear that this requirement is not discriminatory in law, being indistinctly applicable to Community and third country manufacturers, it is equally not wholly evident to me that the effect of such a requirement would in practice impose a greater competitive burden on third country manufacturers than on EU companies.<sup>119</sup>

The AG found that the requirement of EU level validation of alternative methods was “justifiable under Article XX(b) GATT,” in that this requirement satisfied the criterion of necessity<sup>120</sup> “within the meaning of this provision.”<sup>121</sup> In his view, the AG could not see another measure being reasonably available to the EU that would qualify as more consistent with GATT and within the meaning of GATT case law.<sup>122</sup> France had argued that alternative methods should be validated at the OECD level instead of the EC level, and thus qualify as more consistent with GATT.<sup>123</sup> The AG rejected this argument and made the valid point that the legislature was aware of this possibility but had justifiably rejected it.<sup>124</sup> He referred to the Commission Proposal of 2000,<sup>125</sup> where the Commission emphasized the need for alternatives to be endorsed at the EC level given the moral importance of welfare within the EC and the number of years it takes for an existing method to be accepted by all OECD members.<sup>126</sup> Thus, the Commission agreed that regulatory acceptance at the EC level would be more time efficient.<sup>127</sup>

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<sup>115</sup> *Id.* at ¶ 117; *GATT*, *supra* n. 83.

<sup>116</sup> 2005 Op. Adv. Gen. Geelhoed E.C.R. I-04021 at ¶ 117.

<sup>117</sup> *GATT*, *supra* n. 83.

<sup>118</sup> 2005 Op. Adv. Gen. Geelhoed E.C.R. I-04021 at ¶ 117.

<sup>119</sup> *Id.* at ¶ 120.

<sup>120</sup> See World Trade Org. App. Body Rpt., *European Communities-Measures Affecting Asbestos and Asbestos-Containing Products*, pt. VII, art. B, WT/DS135/AB/R (Mar. 12, 2001) (adopted Apr. 5, 2001) (available at [http://www.wto.org/English/tratop\\_e/dispu\\_e/135abr\\_e.pdf](http://www.wto.org/English/tratop_e/dispu_e/135abr_e.pdf)) (giving an example of the necessity test).

<sup>121</sup> 2005 Op. Adv. Gen. Geelhoed E.C.R. I-04021 at ¶ 121.

<sup>122</sup> See *id.* at ¶ 121 (citing World Trade Org. App. Body Rpt., *Korea—Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, WT/DS161/AB/R (Jan. 10, 2001)) (available at <http://docsonline.wto.org/DDFDocuments/t/WT/DS/169ABR.doc>).

<sup>123</sup> 2005 Op. Adv. Gen. Geelhoed E.C.R. I-04021 at ¶ 117.

<sup>124</sup> *Id.* at ¶ 122.

<sup>125</sup> Commn. Eur. Communities, COM (2000) 189 final (Apr. 5, 2000).

<sup>126</sup> 2005 Op. Adv. Gen. E.C.R. I-04021 at ¶ 122.

<sup>127</sup> *Id.* at ¶ 122.

In distinguishing the present case from that of *United States—Import Prohibition of Certain Shrimp and Shrimp Products*,<sup>128</sup> the AG found that the requirement of EU level validation was “adopted in good faith, constituted in the Community legislature’s view the only means of effectively achieving the Directive’s goal of animal protection, and had the explicit aim of [maximizing] acceptance of EU-approved alternative methods at OECD level.”<sup>129</sup> In dismissing the French government’s case on the above arguments, the AG proposed that the ECJ should dismiss the action.<sup>130</sup>

#### D. *The Decision of the European Court of Justice*

The ECJ delivered its decision on May 24, 2005.<sup>131</sup> In dismissing France’s annulment action, the ECJ upheld the legality of the seventh amendment to the Cosmetics Directive.<sup>132</sup> The ECJ looked at settled case law and concluded that partial annulment of an EC Act is only possible if the part for which annulment is sought can be severed from the remainder of the Act.<sup>133</sup> The ECJ concluded that when partial annulment of the EC Act would result in an alteration of the substance of the Act, the requirement of severability is not satisfied.<sup>134</sup> When applying an objective criterion<sup>135</sup> to decide whether partial annulment would result in a substantive alteration of the contested Act, the ECJ found that when the annulment of the contested provision “would objectively alter the very substance of the provisions adopted by the Community legislature,” the contested provision could not be severed.<sup>136</sup> Since Article 4a “constitute[s] one of the principal axes of [the CDA],” severing it would “objectively alter the very substance” of that

<sup>128</sup> World Trade Org. App. Body Rpt., *United States—Import Prohibition of Certain Shrimp and Shrimp Product*, WT/DS58/AB/R (Oct. 12 1998). The French government argued that this case was relevant because the Appellate Body found a requirement that other countries adopt a specific regulatory system that was essentially the same as the Member’s own. 2005 Op. Atty. Gen. Geelhoed E.C.R. I-04021 at ¶ 123. The Appellate Body did this without inquiring to see if such a system was appropriate in light of the conditions of those countries. *Id.*

<sup>129</sup> 2005 Op. Adv. Gen. Geelhoed E.C.R. I-04021 at ¶ 123.

<sup>130</sup> *Id.* at ¶ 125.

<sup>131</sup> Case C-244/03, *Judgment*, 2005 E.C.R. I-04021.

<sup>132</sup> *Id.*

<sup>133</sup> *Id.* at ¶ 12 (citing Case C-29/99, *Commn. European Communities v. Council of the European Union*, 2002 E.C.R. I-11221 at ¶¶ 45, 46; Case C-378/00, *Commn. European Communities v. European Parliament*, 2003 E.C.R. I-00937 at ¶¶ 28, 29; Case C-239/01, *Fed. Republic Germany v. Commn. European Communities*, 2003 E.C.R. I-10333 at ¶ 33).

<sup>134</sup> Case C-244/03, *Judgment*, 2005 E.C.R. I-04021 at ¶ 13 (citing Joined Cases C-68/94 and C-30/95, *French Republic v. Commn. European Communities*, 1998 E.C.R. I-1375, at ¶ 257; Case C-29/99, 2002 E.C.R. I-11221 at ¶ 46; Case C-239/01, 2003 E.C.R. I-10333 at ¶ 34).

<sup>135</sup> See Case C-239/01, 2003 E.C.R. I-10333 at ¶ 37 (for an example of the court using an objective criterion).

<sup>136</sup> See Case C-244/03, *Judgment*, 2005 E.C.R. I-04021 at ¶ 15 (concluding that annulment would “alter the very substance” of the provisions relating to animal testing).



provision, and the court rejected France's argument.<sup>137</sup> The ECJ referred to Recital 18 of the preamble of the CDA, which provides that the provisions of the Directive 95/35/EC—banning the marketing of cosmetic products containing ingredients or combinations of ingredients tested on animals—should be superseded by the provisions of the CDA.<sup>138</sup> The ECJ found that Article 1(2) was intended to “supersede” Article 4(1)(i) of the Cosmetics Directive; thus the insertion of Article 1(2) in the Cosmetics Directive and the deletion of Article 4(1)(i) constituted a non-severable whole.<sup>139</sup> Consequently, the partial annulment of Article 1(2) was not possible and France's action was therefore dismissed as inadmissible.<sup>140</sup>

#### V. THE FUTURE OF ANIMAL TESTING IN COSMETICS IN THE EUROPEAN UNION

By 2009, manufacturers of cosmetic products will no longer be able to test their products on animals in situations where there is a validated alternative to animal testing. Products that were previously tested on animals will continue to be sold. The ban is not retroactive, as it applies only to ingredients and finished products marketed after the 2009 and 2013 cutoff dates. Member States have until 2009 to incorporate the Cosmetics Directive into their respective national legal systems. The method of incorporation is up to each Member State,<sup>141</sup> but once enacted, the Cosmetics Directive is binding in its entirety. Member States may adopt the Cosmetics Directive sooner than 2009,<sup>142</sup> but if a Member State fails to incorporate it by the deadline, it may be subject to fines by the ECJ under the principle of state liability.<sup>143</sup> Until 2009, there will be a near total ban on the testing of products on animals.<sup>144</sup> For those products that do not have a validated alternative to testing on animals by 2009, a four year extension will be

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<sup>137</sup> *Id.*

<sup>138</sup> *Id.* at ¶ 17.

<sup>139</sup> *Id.* at ¶ 16.

<sup>140</sup> *Id.* at ¶ 20.

<sup>141</sup> *CDA*, 2003 O.J. (L66) at 28. For instance, in Ireland, the Cosmetics Directive can be incorporated by way of Statutory Instrument (SI) or Act. *European Communities (Cosmetic Products)* (Amendment No. 5), Regulations 2003, SI No. 553/2003 (Ireland's version of the Cosmetics Directive). Where it alters existing law, an Act is used; otherwise, a SI is used. A SI is brought in by the relevant government minister. This is a more time effective method than introducing a bill.

<sup>142</sup> *CDA*, 2003 O.J. (L66) at 28; see *European Communities (Cosmetic Products)* (Amendment No 5), Regulations 2003, SI No. 553/2003. Although animal testing has been prohibited in the United Kingdom since 1997, the Cosmetics Directive was implemented through the Cosmetics (Safety) Regulations 2004 No. 2152.

<sup>143</sup> See Joined Cases C-46/93 and C-48/93, *Brasserie du Pêcheur SA v. Ger. & Queen v. Sec. State Transp. ex parte Factortame Ltd.*, 1996 E.C.R. I-01029 at ¶¶ 1, 3, 4, 36 (discussing state liability) (available at <http://eur-lex.europa.eu/Notice.do?val=212074>); Steiner, Woods & Twigg-Flesner, *supra* n. 11 at 111–23 (discussing the principle of state liability).

<sup>144</sup> *CDA*, 2003 O.J. (L66) at 28.

allowed.<sup>145</sup> This deadline may be extended if non-animal alternatives are still unavailable by 2013.<sup>146</sup>

Interestingly, leading cosmetics company L'Oreal contends that there is no alternative for toxicity and skin irritation tests.<sup>147</sup> Until alternative testing is introduced, animal tests will be used to test for toxicity and skin irritation.<sup>148</sup> However, in the U.S., the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) has validated alternative tests, the two most important being the Corrisitex®<sup>149</sup> and the Murine Local Lymph Node Assay (LLNA),<sup>150</sup> which determine skin corrosivity and irritation, respectively.<sup>151</sup> In 2001, the European Centre for the Validation of Alternative Methods (ECVAM) completed validation studies resulting in approval by the Commission of three *in vitro* skin corrosivity test methods and an *in vitro* phototoxicity assay.<sup>152</sup>

It is important to note that Article 4a of the CDA does not prevent companies from developing new products. Accordingly, the EU has a list of over eight thousand cosmetic ingredients that do not require animal testing.<sup>153</sup> Therefore, there is no reason why cosmetic companies cannot develop market-safe and innovative new products using these ingredients.

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<sup>145</sup> *Id.*

<sup>146</sup> *Id.*

<sup>147</sup> Naturewatch, *Compassionate Shopping*, [http://www.naturewatch.org/shopping-guide/loreal\\_response.asp](http://www.naturewatch.org/shopping-guide/loreal_response.asp) (accessed Apr. 7, 2007).

<sup>148</sup> *Id.*

<sup>149</sup> Megan Erin Gallagher, *Toxicity Testing Requirements, Methods and Proposed Alternatives*, 26 *Environ. L. & Policy J.* 253, 268–69 (2003).

<sup>150</sup> Natl. Inst. Health, *A Big Step in Reducing Animal Testing: FDA, OSHA and CPSC Accept Alternative Test for Allergic Contact Dermatitis Following Review, Approval by an Independent Scientific Panel*, <http://www.niehs.nih.gov/oc/news/anitest> (accessed Apr. 7, 2007). This test has reduced the number of animals used and virtually eliminates pain and distress. Gallagher, *supra* n. 149, at 268. This test was reviewed in September 1998 and was validated by ICCVAM in February 1999. *Id.* The Environmental Protection Agency (EPA), the U.S. Food and Drug Administration (FDA), and the Occupational Safety and Health Administration (OSHA) announced their acceptance of the LLNA in October 1999. *Id.* at 268.

<sup>151</sup> ICCVAM & NICEATM, *Overview*, <http://iccvam.niehs.nih.gov/about/overview.htm> (accessed Feb. 14, 2007) (on file with *Animal L.*).

<sup>152</sup> *Id.*

<sup>153</sup> See Ltr. from Brit. Union for the Abolition of Vivisection to the Priv. Sec. to Patricia Hewitt, Sec. State, Dept. Trade Indust., *Cosmetics Directive* (Nov. 19, 2001) (available at <http://www.publications.parliament.uk/pa/cm200102/cmselect/cmeuleg/152-xvi/15205.htm>) (“[T]he Commission accepts that there are already more than 8,000 ingredients safely used in cosmetics without the need for any further animal testing.”) (on file with *Animal L.*); Eur. Parl. Comm. on the Env., Pub. Health & Consumer Policy, *Resolution on the Commission Report on the Development, Validation, and Legal Acceptance of Alternative Methods to Animal Experiments in the Field of Cosmetics*, at ¶ 4(a), COM(97) 0182 C4-0369/97 (Oct. 23, 1997) (stating the Cosmetic industry has 8,000 ingredients available to use until validated alternatives are available) (on file with *Animal L.*).

## VI. DIRECTIVE 2003/15/EC: EFFECTIVENESS AND PROBLEMS

The phased introduction of a prohibition on animal testing is a positive move on the part of the EU institutions. The ban is two-fold: it prohibits both the testing of cosmetics on animals and the sale of products (individual ingredients and finished products) that have been tested on animals.<sup>154</sup> However, the CDA is not without its shortcomings, which threaten to denigrate its effectiveness.

The prohibition also applies to products that are imported from outside the EU.<sup>155</sup> This will prove to be troublesome for countries such as the U.S., where the Food and Drug Administration (FDA) requires rigorous testing of certain chemicals before they may be used in cosmetics.<sup>156</sup> It is also possible that a rival company could have a competitor's product tested on animals and thus have it removed from the market.<sup>157</sup> Some believe that the elimination of animal testing will result in the sale of products that may be injurious to the consumer.<sup>158</sup> Arguably, enforcement in relation to third countries will be difficult, and the number of animals that will benefit from the ban is negligible. Independent research estimates that of the 11.6 million animals utilized for experimental or scientific purposes in the EU, only 0.3% are used for cosmetic testing.<sup>159</sup> These tests are carried out on rats, mice, guinea pigs, rabbits, and fish; cosmetic testing is not conducted on dogs, cats, or primates.<sup>160</sup>

The institutions, namely the Council, the Commission, and the Parliament, took different approaches to the wording of the CDA, and in the end, a compromise had to be reached.<sup>161</sup> Both the Commission and the Council argued that the stipulated time periods for a ban on animal testing were overzealous given that suitable alternatives had to be in force by then.<sup>162</sup> The Commission felt that the date of the prohibition "should be postponed . . . if there has been insufficient progress in developing satisfactory methods to replace animal testing scientifically validated as offering an equivalent level of protection for

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<sup>154</sup> CDA, 2003 O.J. (L66) at 28.

<sup>155</sup> Rosholt, *supra* n. 62, at 422.

<sup>156</sup> *Id.*

<sup>157</sup> *Id.*

<sup>158</sup> *Id.*

<sup>159</sup> Commn. European Communities, *Fourth Report from the Commission to the Council and the European Parliament on the Statistics on the Number of Animals used for Experimental and Other Scientific Purposes in the Member States of the European Union*, at 9, COM (2005) 7 final (Jan. 20, 2005) (on file with *Animal L.*).

<sup>160</sup> The European Cosmetic Toiletry & Perfumery Association, *Animal Testing: Can We Do Without?* <http://www.colipa.com/site/index.cfm?SID=15588&OBJ=15756> (accessed Feb. 13, 2007).

<sup>161</sup> Eur. Parl. Conciliation Comm., *Conciliation Report*, Doc. (A5-0001).

<sup>162</sup> See Commn. Eur. Communities, COM (2002) 435 at 4 (the Commission states that the time scale for bans is unrealistic); Council Common Position (EC) No. 29/2002 of 14 February 2002, 2002 O.J. (C 113) at ¶10, 115 (the Council favors a stepwise approach to banning testing because "it is impossible to predict when all necessary alternative methods . . . could be available.").

the consumer.”<sup>163</sup> This argument was consistent with the views of the Economic and Social Committee and the SCCNFP. The SCCNFP argued “that total abolishment of animal tests within 10 years is not feasible from an objective scientific point of view.”<sup>164</sup> The SCCNFP also called for a clear definition, as well as the consistent and correct use of the term *in vitro* throughout the seventh amendment to the Cosmetics Directive.<sup>165</sup> *In vitro* does not necessarily negate the use of animal testing, as many cell cultures and tissue cultures are derived from animals; thus, there is no total replacement of animals in such testing.<sup>166</sup>

The SCCNFP concluded that the deadlines for abolition of animal testing were both “too optimistic and not realistic.”<sup>167</sup> The Parliament, the only institution directly elected by the people of the EU, was seemingly motivated by more political concerns.<sup>168</sup> The Experimental Animals Protection Directive,<sup>169</sup> enacted prior to the CDA, was introduced to harmonize the laws in the Member States in relation to animal testing across all industries.<sup>170</sup> To some, the seventh amendment is superfluous, and its failure to refer to the three Rs—Reduction, Refinement, and Replacement—has been criticized.<sup>171</sup> However, the CDA does call for:

the systematic use of alternative methods, which reduce the animals used or reduce the suffering caused, in those cases where full replacement alternatives are not yet available . . . when these methods offer consumers a level of protection equivalent to that of conventional methods which they are intended to replace.<sup>172</sup>

While the Cosmetics Directive encourages scientific developments to incorporate refinement and reduction, until validated alternatives are introduced, the replacement of animals in cosmetic testing will remain but an aspiration.

## VII. THE UNITED STATES AND ANIMAL COSMETIC TESTING

The U.S. has taken similar action at a state level to ban the testing of cosmetics on animals. The infamous Draize Eye Irritancy Test

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<sup>163</sup> Commn. Eur. Communities, COM (2000) 189 at 6.

<sup>164</sup> SCCNFP, *Opinion Concerning a “Report for Establishing the Timetable for Phasing Out Animal Testing for the Purpose of the Cosmetics Directive” Issued by ECVAM (30/04/2004)*, at 2, SCCNFP/0834/04 (adopted July 1, 2004) (available at [http://ec.europa.eu/health/ph\\_risk/committees/sccp/documents/out285\\_en.pdf](http://ec.europa.eu/health/ph_risk/committees/sccp/documents/out285_en.pdf)).

<sup>165</sup> *Id.* at 2.

<sup>166</sup> *Id.*

<sup>167</sup> *Id.* at 18.

<sup>168</sup> See Rosholt, *supra* n. 62, at 426 (“Parliament maintained that public opinion demanded the bans regardless of the availability of alternatives.”).

<sup>169</sup> Council Directive 86/609, 1986 O.J. (L 358) 1 (EEC) [hereinafter *Experimental Animals Protection Directive*] (available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31986L0609:EN:HTML>).

<sup>170</sup> *Id.*

<sup>171</sup> Rosholt, *supra* n. 62, at 424.

<sup>172</sup> CDA, 2003 O.J. (L 66) at 26.

(Draize test) has been long admonished for its barbaric treatment of rabbits.<sup>173</sup> This test was first developed by John H. Draize, Ph.D., Director of the Dermal and Ocular Toxicity Branch of the FDA.<sup>174</sup>

Draize and his co-workers developed a technique whereby a beauty or household product is applied to a rabbit's eye, skin, or penis over a twenty-four, forty-eight, or seventy-two hour period.<sup>175</sup> In some cases, the observations last from seven to twenty-one days.<sup>176</sup> Rabbits are placed in a holding device which only exposes their heads so that they cannot claw out their eyes or escape.<sup>177</sup> The subject is usually an albino New Zealand white rabbit.<sup>178</sup> The test is carried out to see whether signs of blindness, hemorrhaging, bleeding, swelling, ulceration, and/or discharge occur. Draize was influenced and prompted to develop his infamous test by an article in the Journal of the American Medical Association that discussed the "injurious consumer climate"<sup>179</sup> and reported that insufficient eye testing could result in a number of injuries, ranging from blindness to death.<sup>180</sup>

In most cases, the rabbit is not anaesthetized during the process, and is killed after the test has ended.<sup>181</sup> Such tests are difficult to justify, considering that most of these cosmetic products have already been tested and this duplication is both superfluous and cruel.<sup>182</sup> Interestingly, because rabbits have a different cornea structure<sup>183</sup> and produce a smaller amount of tears than humans, a substance placed in the eye of a rabbit will stay there longer and consequently, the irritancy test may produce different results in comparison to humans.<sup>184</sup> Not only are animals biologically different from humans, but animals of the same species may also have biological differences. This has "led

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<sup>173</sup> Sara Amundson, *Changing Laws to Change Toxicology*, 2002 AV Mag. 15 (Summer 2002) (available at [http://www.aavs.org/images/AV\\_Text.qxd.1.pdf](http://www.aavs.org/images/AV_Text.qxd.1.pdf)); see also Delcianna J. Winders, Student Author, *Combining Reflexive Law and False Advertising Law to Standardize "Cruelty Free" Labeling of Cosmetics*, 81 N.Y.U. L. Rev. 454 (2006) (suggesting strategies to diminish false cruelty-free advertising); Stacy E. Gillespie, Student Author, *A Cover-Girl Face Does Not Have to Begin with Animal Cruelty: Chapter 476 Gives Legal Force to Alternative Testing Methods*, 32 McGeorge L. Rev. 461 (2001) (considering California Chapter 476's effect on animal testing for cosmetics).

<sup>174</sup> Crystal Miller, *The Dreaded Draize Eye Test: Harming the Eye of the Beholder*, 2002 AV Mag. 10 (Summer 2002) (available at [http://www.aavs.org/images/AV\\_Text.qxd.1.pdf](http://www.aavs.org/images/AV_Text.qxd.1.pdf)).

<sup>175</sup> *Id.* at 10.

<sup>176</sup> *Id.*; Gallagher, *supra* n. 149, at 258.

<sup>177</sup> Gillespie, *supra* n. 173, at 464.

<sup>178</sup> *Id.*

<sup>179</sup> *Id.*

<sup>180</sup> *Id.*

<sup>181</sup> Miller, *supra* n. 174, at 10.

<sup>182</sup> See Gillespie, *supra* n.173, at 464 (noting that these duplicated tests are being carried out for data proposes only).

<sup>183</sup> G. Langley & C. Langley, *Cosmetics Testing on Animals in France, Cosmetics Testing on Animals—A Scientific Critique*, [http://www.experimentation-animale.org/english/gbcosm\\_chap4.html](http://www.experimentation-animale.org/english/gbcosm_chap4.html) (accessed Apr. 7, 2007).

<sup>184</sup> *Id.*

to the premature approval of chemicals and products which later prove to be harmful and fatal to humans.”<sup>185</sup>

The use of the Draize test has long been questioned in the U.S., as neither the FDA nor federal law requires that the finished cosmetic products be tested prior to their marketing or sale.<sup>186</sup> However, the “FDA strongly urges cosmetic manufacturers to conduct whatever toxicological or other tests are appropriate to substantiate the safety of their cosmetics.”<sup>187</sup> Some companies use the testing information for data purposes in the event of a consumer reporting an adverse reaction to a product.<sup>188</sup>

#### A. Senator Jack O’Connell and S.B. 2082

There have been four attempts to criminalize the Draize test in the state of California.<sup>189</sup> The final Senate Bill, S.B. 2082, was signed by Governor Gray Davis on September 16, 2000.<sup>190</sup> S.B. 2082 has been hailed as a small but significant step, as it is the first statute in the U.S. to curtail animal testing in the cosmetic industry.<sup>191</sup> S.B. 2082 requires manufacturers and their contract testing facilities to stop using animals in cosmetics testing when alternative validated testing methods are available.<sup>192</sup> It provides for a maximum civil penalty of \$5000 and injunctive relief for breach of the bill.<sup>193</sup> It also allows successful parties to recover costs and attorneys’ fees.<sup>194</sup> S.B. 2082 does not apply to tests carried out in the interest of medical and pharmaco-

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<sup>185</sup> See Gallagher, *supra* n. 149, at 260 (referring to the findings of the U.S. General Accounting Office, which found that fifty-two percent of all new drugs over a ten year period had serious toxic and fatal effects that were not discovered in tests carried out on animals).

<sup>186</sup> Miller, *supra* n. 174, at 11.

<sup>187</sup> U.S. Food & Drug Administration Ctr. Food Safety & Applied Nutrition, *Cosmetic Handbook: Regulatory Requirements for Marketing Cosmetics in the United States*, <http://www.cfsan.fda.gov/~dms/cos-hdb1.html> (1992) [hereinafter *FDA*].

<sup>188</sup> Miller, *supra* n. 174, at 11.

<sup>189</sup> Gillespie, *supra* n. 173, at 462 n. 10 (Cal. Assembly 2461 (1989) (criminalizing the Draize test); Cal. Assembly 110 (1991) (narrowing criminal repercussions for use of the Draize test); Cal. Sen. 777 (1999) (dropped by Senator O’Connell in favor of Cal. Sen. 2082, Reg. Sess. (Feb. 25, 2000)); Cal. Sen. Jud. Comm., *Animal Testing: Alternative Methods SB 2082*, Reg. Sess. 2 (Apr. 23, 2000) (available at [http://www.leginfo.ca.gov/pub/99-00/bill/sb\\_2082\\_cfa\\_20000426\\_103549\\_sen\\_comm.html](http://www.leginfo.ca.gov/pub/99-00/bill/sb_2082_cfa_20000426_103549_sen_comm.html)).

<sup>190</sup> The Bill added § 1834.8 to the California Civil Code, relating to animal testing. Cal. Civ. Code § 1834.8 was renumbered to Cal. Civ. Code § 1834.9 in 2001. Cal. Civ. Code Ann. § 1834.9(9) (West 2007).

<sup>191</sup> Gillespie, *supra* n. 173, at 474.

<sup>192</sup> Cal. Civ. Code Ann. § 1834.9(a) (West Supp. 2007) (validating alternatives would be those that are accepted by the ICCVAM and adopted by the responsible federal regulatory agency(ies)).

<sup>193</sup> *Id.* at § 1834.9(b).

<sup>194</sup> *Id.* at § 1834.9(d). Those who can bring suit for injunctive relief include the Attorney General, the district attorney of the county in which the violation is alleged to have been occurred, or a city attorney of a city or a city and county with a population of over 750,000. *Id.*

logical research and development.<sup>195</sup> In addition, it does not prohibit the use of animal tests to comply with the requirements of state agencies.<sup>196</sup>

S.B. 2082 came in the wake of three failed attempts by Senator Jack O'Connell to prohibit animal testing. In 1989 and 1990, O'Connell introduced two bills that attempted to criminalize the use of the Draize test and the skin irritancy test.<sup>197</sup> Both bills were adopted by the legislature but were vetoed by then-Governor Pete Wilson, who argued that no validated alternative to animal testing existed and that consumer safety was of paramount importance.<sup>198</sup> The second bill, Assembly Bill (A.B.) 110, was similar to the first bill, but narrowed its scope to prohibit the use of the Draize and skin irritancy tests for household cleaning products and cosmetics.<sup>199</sup> A.B. 110 reduced the criminal sanction proposed in A.B. 2461 (the first bill) to a misdemeanor and a fine not exceeding \$2000.<sup>200</sup> Again, then-Governor Wilson vetoed the bill, arguing that there was no feasible validated alternative to animal testing in the foreseeable future.<sup>201</sup> In 1999, Senator O'Connell authored a third bill, S.B. 777, but this was subsequently shelved in favor of S.B. 2082.<sup>202</sup> S.B. 777 had almost reached a compromise, but the deadline lapsed, and O'Connell re-introduced the bill as S.B. 2082 and resumed negotiations.<sup>203</sup>

An instigating factor in the creation of S.B. 2082 was enactment at the federal level of the National Institutes of Health Revitalization Act of 1993 (NIHRA).<sup>204</sup> The NIHRA recognized the fact that the majority of testing is carried out by regulatory agencies, and in doing so, it directed the National Institute of Environmental Health Sciences to establish an interagency to evaluate the feasibility of developing valid alternatives to animal testing.<sup>205</sup> This agency became known as ICCVAM and was originally an ad hoc committee, but the ICCVAM Authorization Act of 2000<sup>206</sup> placed the agency on a permanent foot-

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<sup>195</sup> *Id.* at § 1834.9(e).

<sup>196</sup> *Id.* at § 1834.9(c).

<sup>197</sup> Cal. Sen. Jud. Comm. Rpt., 1999–2000 Sen., Reg. Sess. 2 (Apr. 25, 2000) (available at [http://info.sen.ca.gov/pub/99-00/bill/sen/sb\\_2051-2100/sb\\_2082\\_cfa\\_20000426\\_103549\\_sen\\_comm.html](http://info.sen.ca.gov/pub/99-00/bill/sen/sb_2051-2100/sb_2082_cfa_20000426_103549_sen_comm.html)).

<sup>198</sup> *See id.* at 6 (quoting Gov. Wilson's reason for vetoing the bill).

<sup>199</sup> *Id.*

<sup>200</sup> *Id.*

<sup>201</sup> *Id.* at 6–7.

<sup>202</sup> *Id.* at 7.

<sup>203</sup> Cal. Sen. Jud. Comm. Rpt. 1999–2000 at 7.

<sup>204</sup> Pub. L. No. 103-43, 107 Stat. 122 (June 10, 1993).

<sup>205</sup> 42 U.S.C. § 283e (2000).

<sup>206</sup> Pub. L. No. 106-545, 114 Stat. 2721 (Dec. 19, 2000).

ing.<sup>207</sup> As mentioned in Section IX, the ICCVAM has already validated two alternative tests, the Corrisitex® and the LLNA.<sup>208</sup>

*B. Chapter 476-Civil Code Section 1834.9*

S.B. 2082 was given the force of law in 2000, when Chapter 476 was enacted, and it later became California Civil Code § 1834.9.<sup>209</sup> Chapter 476 prohibits the use of animals in cosmetic testing where alternative test methods have been scientifically validated by the ICCVAM and subsequently adopted by the appropriate federal regulatory agency.<sup>210</sup> The medical and scientific communities were critical of the wording of S.B. 2082, which gave an exemption to medical and pharmacological research and development, as they found it to be “dangerously vague and overbroad.”<sup>211</sup> The medical community felt that the law needed further defining, lest it hamper medical and pharmacological advancements in research and development.<sup>212</sup>

Senator O’Connell took the views of the medical and scientific industry and introduced an amended version of S.B. 2082.<sup>213</sup> The original version of S.B. 2082 defined the medical research exemption in the following terms: “research related to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of humans and animals.”<sup>214</sup> The May 3, 2000 amended version added the following language to S.B. 2082: “or related to the development of biomedical products, devices, or drugs as defined in Section 321(g)(1) of Title 21 of the United States Code.”<sup>215</sup>

<sup>207</sup> 42 U.S.C. § 285l-3(a) (2000); see ICCVAM & NICEATM, *supra* n. 151 (stating that ICCVAM consists of forty-seven representatives from fifteen U.S. federal agencies, a list of which is available at [http://iccvam.niehs.nih.gov/about/agencies/ni\\_AgRepS.htm](http://iccvam.niehs.nih.gov/about/agencies/ni_AgRepS.htm)).

<sup>208</sup> See ICCVAM & NICEATM, *supra* n. 151 (discussing the validation of the two alternative tests).

<sup>209</sup> Cal. Civ. Code Ann. § 1834.9.

<sup>210</sup> *Id.*

<sup>211</sup> Gillespie, *supra* n. 173, at 463 n. 13.

<sup>212</sup> *Id.*

<sup>213</sup> Cal. Sen. 2082, 1999–2000 Reg. Sess. (May 3, 2000) (available at [http://leginfo.ca.gov/pub/99-00/bill/sen/sb\\_2051-2100/sb\\_2082\\_bill\\_20000503\\_amended\\_sen.pdf](http://leginfo.ca.gov/pub/99-00/bill/sen/sb_2051-2100/sb_2082_bill_20000503_amended_sen.pdf)).

<sup>214</sup> Cal. Sen. 2082, 1999–2000 Reg. Sess. (Feb. 25, 2000) (available at [http://leginfo.ca.gov/pub/99-00/bill/sen/sb\\_2051-2100/sb\\_2082\\_bill\\_20000225\\_introduced.pdf](http://leginfo.ca.gov/pub/99-00/bill/sen/sb_2051-2100/sb_2082_bill_20000225_introduced.pdf)).

<sup>215</sup> Cal. Sen. 2082, 1999–2000 Reg. Sess. (May 3, 2000). The bill was amended again in assembly before being enacted into law. Cal. Sen. 2082, 1999–2000 Reg. Sess. (June 28, 2000) (available at [http://leginfo.ca.gov/pub/99-00/bill/sen/sb\\_2051-2100/sb\\_2082\\_bill\\_20000628\\_amended\\_asm.pdf](http://leginfo.ca.gov/pub/99-00/bill/sen/sb_2051-2100/sb_2082_bill_20000628_amended_asm.pdf)). The assembly amendment added additional language to the definition of medical research:

Medical research does not include the testing of an ingredient that was formerly used in a drug, tested for the drug use with traditional animal methods to characterize the ingredient and substantiate its safety for human use, and is now proposed for use in a product other than a biomedical product, medical device, or drug.

Cal. Civ. Code Ann. § 1834.9; see 21 U.S.C. §321(g)(1) (2000) (defining “drug”).



*C. Animal Welfare Groups and Standing*

Another interesting amendment introduced by Chapter 476 relates to the disempowerment of animal welfare groups to initiate proceedings against companies that allegedly breach the Chapter.<sup>216</sup> Under S.B. 2082, “any entity lawfully organized under the federal Internal Revenue Code as a 501(c)(3) or 501(c)(4) organization for the purpose of protecting or providing for the welfare of animals” had *locus standi* to bring an action against offending companies.<sup>217</sup> Under pressure from opposition in the medical and pharmaceutical industry, Senator O’Connell removed the right of animal welfare groups to initiate civil proceedings “upon the belief that animal advocate groups would instigate frivolous litigation by using Chapter 476 as a tool for industry harassment.”<sup>218</sup>

### VIII. EUROPEAN UNION AND CALIFORNIA LEGISLATION COMPARED

While the scope and effectiveness of the seventh amendment to the Cosmetics Directive has a number of limitations as discussed above, the amendment is nevertheless a medium through which new validated and suitable alternatives to animal testing can be developed. Article 2 of the Cosmetics Directive expressly requires manufacturers in the EC to safely test their products before placing them on the market, so as not to “cause damage to human health when applied under normal or reasonably foreseeable conditions of use . . . .”<sup>219</sup> Article 6 of the CDA replaced Section 7(a)(1)(d) of the 1976 Cosmetics Directive to provide for an assessment of human health of the finished product.<sup>220</sup> In order to achieve this, “the manufacturer shall take into consideration the general toxicological profile of the ingredients, their chemical structure and their level of exposure.”<sup>221</sup> Article 6 also requires manufacturers to perform a specific assessment for children under the age of three and for products intended exclusively for use in external intimate hygiene.<sup>222</sup>

The U.S., on the other hand, does not explicitly require such an assessment. Under the Federal Food, Drug, and Cosmetic Act of 1938, manufacturers are under no obligation to carry out a safety assessment.<sup>223</sup> The FDA does, however, strongly advocate the use of toxicological or other appropriate tests by cosmetic manufacturers to

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<sup>216</sup> Gillespie, *supra* n. 173, at 471.

<sup>217</sup> Cal. Sen. 2082, 1999–2000 Reg. Sess. (Feb. 25, 2000) (as introduced, but not enacted).

<sup>218</sup> See Gillespie, *supra* n. 173, at 471 (making the point that these objections came before the medical exemption was refined under Chapter 476).

<sup>219</sup> Cosmetics Directive, art. 2, 1976 O.J. (L 262) at 173.

<sup>220</sup> CDA, 2003 O.J. (L66) at 30.

<sup>221</sup> *Id.*

<sup>222</sup> *Id.*

<sup>223</sup> 21 U.S.C. §§ 301–397 (2000).

substantiate the safety of their cosmetics.<sup>224</sup> Failure to adequately substantiate the safety of a cosmetic product may result in the product being considered misbranded and thus subject to regulatory action, unless the label bears the following statement: “Warning—The safety of this product has not been determined.”<sup>225</sup>

California Civil Code § 1834.9 applies not only to cosmetics, but also to pesticides and other household products.<sup>226</sup> The Cosmetics Directive is more limited, as it applies specifically to cosmetic products, even though the earlier Experimental Animals Protection Directive was introduced to harmonize the laws in the Member States in relation to animal testing across all industries.<sup>227</sup> Arguably, the EU felt that little progress was being made and an impetus for reform was needed. The Cosmetics Directive, given its specific ambit, does not have a medical research exception. Article 1(2) of the CDA introduces Article 4a(2.4)(a) into the Cosmetics Directive and provides for an exception in situations where “the ingredient is in wide use and cannot be replaced by another ingredient able to perform a similar function[.]”<sup>228</sup>

Subsection (b) further adds that “the specific human health problem is substantiated and the need to conduct animal tests is justified and is supported by a detailed research protocol proposed as the basis for the evaluation.”<sup>229</sup> The Commission, after consultation with the SCCNFP, may allow such an exception in the form of a reasoned decision.<sup>230</sup> The French government, in the *French Republic v. European Parliament and the Council of the European Union* case, perceived a defect in this process and questioned its effectiveness in light of time and practicality.<sup>231</sup> It has been argued that during this time, an unreasonable risk to human health could arise.<sup>232</sup> The practicalities of the exception have to be worked out.

Section 1834.9 of the California Civil Code allows for a civil penalty not exceeding \$5000 and injunctive relief for a violation of the provision.<sup>233</sup> The position in the EU is somewhat different. The principle method by which infringements of EU law are pursued is through Article 226.<sup>234</sup> Under Article 226, the Commission can bring a Member State to task if they have failed to fulfill an obligation under the Treaty.<sup>235</sup>

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<sup>224</sup> *FDA*, *supra* n. 187.

<sup>225</sup> *Id.*

<sup>226</sup> Cal. Civ. Code Ann. § 1834.9(a) (applying to manufacturers and contract testing facilities).

<sup>227</sup> *Experimental Animals Protection Directive*, 1986 O.J. (L 358) 1 (EEC).

<sup>228</sup> *CDA*, 2003 O.J. (L 358) at 29.

<sup>229</sup> *Id.* at 29.

<sup>230</sup> Cosmetics Directive, art. 4a(2.4), 1976 O.J. (L 262) at 174.

<sup>231</sup> 2005 Op. Adv. Gen. Geelhoed E.C.R. I-04021 at ¶ 36.

<sup>232</sup> *Id.*

<sup>233</sup> Cal. Civ. Code Ann. § 1834.9(d).

<sup>234</sup> EC Treaty, *supra* n. 11, at art. 226.

<sup>235</sup> *Id.*

The Commission can then deliver a reasoned opinion on the matter after giving the state involved the opportunity to submit its observations.<sup>236</sup> If found to be in default of EC law, the Member State concerned must rectify the situation without delay.<sup>237</sup> If the Member State does not comply with the opinion within the time period laid down, the Commission can bring the matter before the ECJ.<sup>238</sup> If a Member State incorrectly transposes a directive, is late in complying, or improperly implements the directive, the Commission has the power under Article 226 to request immediate resolution of the situation.<sup>239</sup> If a satisfactory result is not achieved, the matter is referred to the ECJ.<sup>240</sup> Article 226 is not a punitive measure, but rather seeks compliance by Member States of their EC obligations. The action is taken against the state, with “state” interpreted in the broadest sense: executive, judicial and legislative.<sup>241</sup>

#### A. *Certifying Methods of the European Union and California*

During the 1990s, the impetus to find validated alternatives to animal testing waned in the U.S. The National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) has been in operation since 1998.<sup>242</sup> Its European counterpart, the ECVAM, was set up some five years previously.<sup>243</sup> The NICEATM has collaborated with the ICCVAM on finding suitable validated alternatives.<sup>244</sup>

It is interesting to note there have been situations where the ECVAM has accepted a validated alternative, and in response to this, the ICCVAM and NICEATM have engaged in an “expedited review process” for validation in the U.S.<sup>245</sup> Recently, the ECVAM approved three new validated alternatives—the EpiDerm™ human skin model, the EPISKIN™ human skin model, and the mouse skin integrity function test [SIFT]—for *in vitro* skin corrosivity tests.<sup>246</sup> These tests are

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<sup>236</sup> *Id.*

<sup>237</sup> Case 69/86, *Commn. v. Italian Republic*, 1987 E.C.R. 780 at ¶8.

<sup>238</sup> EC Treaty, *supra* n. 11, at art. 226.

<sup>239</sup> *Id.*; see e.g. Joined Cases C-6/90 and C-9/90, *Francovich v. Italy*, 1991 E.C.R. I-5357 (finding state liability for failure to transpose a directive); Joined Cases C-46/93 and C-48/93, 1996 E.C.R. I-01029 (discussing state liability).

<sup>240</sup> EC Treaty, *supra* n. 11, at art. 226.

<sup>241</sup> Gerrit Betlam, *The King Can Do Wrong: State Liability for Breach of European Community Law in the Post-Francovich Era*, 1996 4 Web J. Current Leg. Issues, <http://webjcli.ncl.ac.uk/1996/contents4.html> (Sept. 30, 1996) (“Regardless of what organ of the State is responsible for the unlawful act or omission, the executive, the judiciary or the legislature, any case in which a Member State breaches Community law is in principle covered by the liability inherent in the system of the Treaty.”).

<sup>242</sup> Natl. Inst. Environ. Health Sci., *About NICEATM*, [http://iccvam.niehs.nih.gov/about/about\\_NICEATM.htm](http://iccvam.niehs.nih.gov/about/about_NICEATM.htm) (last updated Apr. 6, 2007).

<sup>243</sup> ECVAM, *supra* n. 50.

<sup>244</sup> Natl. Inst. Environ. Health Sci., *supra* n. 242.

<sup>245</sup> Gallagher, *supra* n. 149, at 265.

<sup>246</sup> ICCVAM, *supra* n. 151.

expected to receive regulatory acceptance in 2007–2008.<sup>247</sup> A similar development has taken place in the U.S., where the NICEATM and ICCVAM have been reviewing and evaluating the EpiDerm™ and EPISKIN™ models.<sup>248</sup> Cooperation between EU and U.S. agencies will hopefully result in the approval of validated alternatives in a fast and efficient manner, while creating a uniform set of international guidelines.

Once these validated alternatives have been approved by the ICCVAM and NICEATM, they will then become a part of California law.<sup>249</sup> There is, however, an exception in the law for medical research, which allows for the continuation of animal testing for that purpose.<sup>250</sup> Hopefully by 2009, both the ECVAM and ICCVAM will have created a cohesive set of validated alternatives that will reduce and, in the future, replace the use of animals in cosmetic testing. By working together, the two agencies can expedite the process to create validated alternatives that do not compromise consumer safety and health.

#### IX. FUTURE DEVELOPMENTS

The scientific community is continually developing alternative testing methods. In the 1990s, the three Rs were developed: Replacement, Reduction, and Refinement.<sup>251</sup> Replacement involves the use of cell cultures, reduction involves reducing the number of animals used, and refinement is the improvement of husbandry and procedures that will reduce or abolish the pain and suffering caused to animals.<sup>252</sup>

While all three approaches have merit, “replacement and refinement are generally accepted as being more morally important than mere reduction in the numbers of animals used.”<sup>253</sup> The use of tissue cultures, computer models of bodily functions, magnetic resonance imaging, and organ cultures have been used to reduce the numbers of animals used in research.<sup>254</sup> While these methods apply to laboratory testing in general, perhaps the EU could investigate their viability as validated alternatives for cosmetic products.

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<sup>247</sup> *Executive Summary*, in *Alternative (Non-Animal) Methods for Cosmetics Testing: Current Status and Future Prospects, A Report Prepared in the Context of the 7th Amendment to the Cosmetics Directive for Establishing the Timetable for Phasing Out Animal Testing* 33 Alt. Laboratory Animals 1, 9 (Chantra Eskes & Valerie Zuang eds., Fund for the Replacement of Animals in Med. Experiments Supp. 2005) (on file with *Animal L.*).

<sup>248</sup> ICCVAM & NICEATM, *EPISKIN, and the Rat Skin Transcutaneous Electrical Resistance (TER) Assay: Overview, Performance Standards and Reports*, [http://iccvam.nih.gov/methods/dermal/epiderm\\_standard.htm](http://iccvam.nih.gov/methods/dermal/epiderm_standard.htm) (accessed Mar. 11, 2007).

<sup>249</sup> Cal. Civ. Code Ann. § 1834.9(a) (stating that once ICCVAM has validated an alternative to animal testing manufacturers cannot continue testing on animals).

<sup>250</sup> *Id.* at § 1834.9(e). Cal. Civ. Code Ann. § 1834.9(f)(5) defines “medical research.”

<sup>251</sup> Richard D. Ryder, *Specieism in the Laboratory*, in *In Defense of Animals: The Second Wave* 87, 96 (Peter Singer ed., Blackwell Publ. Ltd. 2006).

<sup>252</sup> *Id.* at 96.

<sup>253</sup> *Id.*

<sup>254</sup> *Id.*

It is important to note that animals can react differently than humans to certain substances.<sup>255</sup> For example, rats have different skin and hair structures than humans.<sup>256</sup> As a result, tests for skin absorption on rats “invariably over-estimate skin penetration in humans.”<sup>257</sup> Similar criticisms have been made of skin corrosivity and irritancy tests, as animals differ from humans in their immune, physiological, and genetic make-up.<sup>258</sup> Consequently, there can be variations in the response to potentially harmful chemicals, making it difficult to predict how a human will react to the same substance.<sup>259</sup> Rabbits are commonly used for irritancy tests; however, the rabbit is a “notoriously poor predictor of human skin irritation.”<sup>260</sup>

Perhaps human testing offers a more ethical alternative. Humans are often used in clinical trials for product testing, but few are used in cosmetic testing.<sup>261</sup> Human volunteers have also been used in skin irritancy and sensitization tests; testers ensure their safety by using data from earlier animal or *in vitro* toxicity tests.<sup>262</sup>

## X. CONCLUSION AND COMMENTARY

While the judgment in *France v. Parliament and Council* focused on the technicalities of partial annulment, the case has highlighted recent developments in the protection of animals at the EU level.<sup>263</sup> Proponents of animal welfare have welcomed the recent amendment to the Cosmetics Directive.<sup>264</sup> Hopefully by 2009, valid alternatives to animal testing will have been found. The use of scientific developments and human volunteers would provide a more ethical, moral, and accurate alternative and result in safer cosmetic products for the consumer. By 2013, there should be an almost complete prohibition on the use of animals in cosmetic testing, irrespective of alternatives.<sup>265</sup> The Commission’s recognition of animal welfare is an important issue, and its proposal to continue to examine animal welfare issues in future proposals is a much welcomed development.

The recent developments in California provided an interesting comparative analysis. The omission of standing for animal welfare groups in California law means that such groups will have grave difficulties filing suit.<sup>266</sup> Chapter 476, although “a miniscule step in ending

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<sup>255</sup> Langley & Langley, *supra* n. 183, at § 2.

<sup>256</sup> *Id.*

<sup>257</sup> *Id.*

<sup>258</sup> *Id.* at § 3.

<sup>259</sup> *Id.*

<sup>260</sup> *Id.* at § 3.

<sup>261</sup> Langley & Langley, *supra* n. 183, at § 10.

<sup>262</sup> *Id.*

<sup>263</sup> Case C-244/03, *Judgment*, 2005 E.C.R. I-04021.

<sup>264</sup> See e.g. Tina Nelson, *First Word*, 2002 AV Mag. 1 (Summer 2002) (describing animal welfare society’s praise of the Cosmetics Directive).

<sup>265</sup> *CDA*, 2003 O.J. (L 66) at 30.

<sup>266</sup> Gillespie, *supra* n. 173, at 471.

the use of animals in safety and efficacy testing . . . sets a precedent for [the] industry."<sup>267</sup> With New York following suit, it may only be a matter of time before other states enact similar legislation.<sup>268</sup>

Although the recent amendments to the Cosmetics Directive will not come into force until 2009,<sup>269</sup> the prohibition of animal testing in cosmetics in the EU has become an important policy objective for the Commission, a progression that would once have seemed improbable in the parlance of the common market. Despite criticism, the Cosmetics Directive represents a tangible effort by the Council, the Commission, and the Parliament to give cognizance to animal welfare as a discrete policy area.

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<sup>267</sup> Miller, *supra* n. 174, at 15.

<sup>268</sup> *See id.* (stating that Assemblyman Pete Grannis (D-NY) has introduced similar legislation in New York).

<sup>269</sup> CDA, 2003 O.J. (L66) at 26.