EU Cosmetics Directive and the Ban on Animal Testing: Compliance, Challenges, and the GATT as a Potential Barrier to Animal Welfare

Jennifer Klein

I. OVERVIEW OF THE EU COSMETICS DIRECTIVE ........................................... 253
   A. Purpose of the Directive ........................................................................... 254
   B. Definition of “Cosmetics” Products Covered by the Directive . 255
   C. Elements of the Directive: Regulated Conduct ........................................ 257
      1. The Testing Ban .................................................................................. 257
      2. The Marketing Ban ............................................................................. 257
      3. The Importation Ban ......................................................................... 258
   D. Stages of Implementation ...................................................................... 258
      1. Conduct Prohibited as of 2009 ........................................................... 259
      2. Conduct Prohibited in 2013 ................................................................. 260
      3. Use of Alternative Methods and Exceptions ..................................... 261

II. CHALLENGES IN THE IMPLEMENTATION OF DIRECTIVE 2003/15 ........ 262
   A. Challenges in EU Member States ......................................................... 262
      1. Exceptions to the Ban on Animal Testing for Cosmetics ..................... 262
      3. EU Cosmetic Companies’ Preparation for the Ban ......................... 263
   B. Compliance Within the EU: Will the EU Member States be Able to Meet Directive 2003/15’s 2013 Deadline? ...................... 264
      2. The Unsuccessful French Challenge to Directive 2003/15265

III. CHALLENGES COMPLYING WITH DIRECTIVE 2003/15 IN THE UNITED STATES .............................................................................................. 266
   A. The Ban on Importation of Animal-Tested Cosmetic Products………………... 266
   B. Consequences of the Importation Ban in the United States .......................... 266
   C. Possible U.S. Responses to the Importation Ban ...................................... 268
      1. Legal Challenge Under the GATT ...................................................... 268
EU COSMETICS DIRECTIVE AND THE BAN ON ANIMAL TESTING: COMPLIANCE, CHALLENGES, AND THE GATT AS A POTENTIAL BARRIER TO ANIMAL WELFARE

The European Commission signed European Union (“EU”) Directive 76/768 (the “Cosmetics Directive”) into law in 1976 in a broad effort to regulate the European cosmetic industry. In 1993, the European Commission amended the Cosmetics Directive with Directive 93/35, which originally sought to end animal testing for cosmetic products by the year 1998. This was the Commission’s first attempt to regulate animal testing for cosmetic products. Despite the original implementation date, two subsequent amendments to the Cosmetics Directive have delayed the Commission’s goal of ending animal testing in the cosmetic industry. The Commission postponed the ban once in 2000 and again in 2003.

The European Commission enacted Directive 2003/15 in 2003 as part of the EU’s effort to reduce animal testing for cosmetic products. Directive 2003/15, the seventh amendment to the Cosmetics Directive, provides the

---


3 See generally id.


7 Although the Commission has amended the Cosmetics Directive numerous times since it passed Directive 2003/15 in 2003, the purpose of those amendments is to adapt the Annexes to technical progress and not to push back or change implementation dates. See EUROPEAN
most recent implementation deadlines to end animal testing for cosmetic products in the EU.\(^8\) This Note will focus mainly on Directive 2003/15 because it provides the deadlines with which cosmetic companies must comply.\(^9\) This Directive takes effect in phases until 2013 and will eventually result in a total ban on the marketing and sale of animal-tested cosmetic products.\(^10\) Directive 2003/15 also bans the importation of animal-tested cosmetic products and products containing animal-tested ingredients.\(^11\) This Note will also focus on the importation ban and the challenges it presents for the United States because the importation ban has the potential to create economic difficulties and trade problems for the United States and other third-party countries.

In Part I, this Note will set forth an overview of the Cosmetics Directive. This Part provides the analytical framework for Part II, which will explore possible issues with compliance within the EU cosmetic industry. Part III will focus on Directive 2003/15’s effects in the United States, address problems with U.S. compliance, and explore possible compliance solutions. This Note provides two potential solutions to the issue of U.S. compliance: 1) a U.S. challenge to this Directive under the GATT or 2) U.S. compliance by using non-animal alternative testing methods. This Note will also briefly discuss alternative options in the event that neither of the above-mentioned options proves feasible or desirable for the United States. Finally, this Note will explore alternative testing methods that could reduce animal testing in the United States, some of which are already in use in the EU. This Note will ultimately conclude that for ethical and economic reasons, U.S. cosmetic companies should comply with the Directive 2003/15 by adopting non-animal testing methods.

I. OVERVIEW OF THE EU COSMETICS DIRECTIVE

Since its implementation in 1976, the Cosmetics Directive has regulated the cosmetic industry in the EU, setting guidelines for both the sale and marketing of cosmetics.\(^12\) In 2003, the European Council issued Directive 2003/15, the seventh amendment to the Cosmetics Directive.\(^13\) An overwhelming majority of the European Parliament approved this

---

\(^8\) Id.


\(^10\) Id.

\(^11\) See id.


amendment, and animal rights activists called it “one of the most significant pieces of EU legislation on animal welfare.”

Directive 2003/15 imposes three bans regulating animal testing: the testing ban, which prohibits animal tests on final products as well as the ingredients that make up those products; the marketing ban, which prohibits the marketing of animal-tested cosmetic products; and the ban on all imported products that have been tested on animals. This Part will explore in more detail the purpose of Directive 2003/15, the definition of “cosmetics” under EU law, the elements of Directive 2003/15, and the stages of implementation.

A. Purpose of the Directive

One basis upon which the Commission enacted Directive 2003/15 is the Protocol on Protection and Welfare of Animals (“the Protocol”), which the Treaty of Amsterdam annexed to the Treaty Establishing the European Community. The Protocol provides that the European Community and Member States must give full consideration to animal welfare in implementing Community policies. Directive 2003/15 officially recognizes the Protocol’s mandate, as well as the rights that some Member States had already accorded to animals prior to 2003. For example, in 2002, Germany added a constitutional provision specifically protecting animal rights. The provision formally imposed a duty upon the state to ensure continued animal welfare. Laws such as Germany’s constitutional provision work alongside Directive 2003/15 to fulfill the EU’s animal welfare goals. In fact, as of 2008, a number of EU Member States listed national legislation as a reason why no animal testing was carried out within that nation’s borders.

17 Id. ¶ 2.
18 Id.
19 Id.
20 GRUNDGESETZ FÜR DIE BUNDESREPUBLIK DEUTSCHLAND [GRUNDGESETZ] [GG] [BASIC LAW], May 23, 1949, BGB1.1 (Ger.), art. 20(a) [hereinafter BASIC LAW]. Article 20(a) was amended to read: “[t]he state takes responsibility for protecting the natural foundations of life and animals in the interest of future generations.” Id. (emphasis added); Germany to Grant Animal Rights, BBC News (May 17, 2002), http://news.bbc.co.uk/2/hi/europe/1993941.stm.
21 BASIC LAW, supra note 20; Germany to Grant Animal Rights, supra note 20.
The goal of Directive 2003/15, in accordance with Directives 86/609 and 93/35, is to abolish animal testing experiments for cosmetic products. In the pursuit of this goal, the prohibition of such experiments will become effective in the Member States through compliance with EU’s animal testing ban provisions as well as national legislation.

B. Definition of “Cosmetics” Products Covered by the Directive

Directive 2003/15 does not prohibit animal testing for all products generally. Rather, it applies only to animal testing for cosmetics, but does not explicitly prohibit animal testing for “drugs”—in fact, under some circumstances the EU and other countries’ laws require animal testing for drugs. Considerable debate exists regarding what products constitute “drugs” versus “cosmetics.” Regulations on the testing of “drugs” are much more stringent than those regulating “cosmetics.” Since consumers generally ingest or absorb drugs into their bodies, these products present a greater risk of harm to consumers. This increased risk to human health justifies, at least to some extent in the eyes of the law, the use of animals to ensure drug product safety.

The Cosmetics Directive defines “cosmetics” as:

Any substance or preparation intended for placing in contact with the various external parts of the human body . . . or with the teeth and the mucous membranes of the oral cavity with a


25 See generally id.

26 Id.

27 However, some progress has also been made in relation to animal testing generally, including testing for drugs. For example, the European Parliament passed a new law providing that “[t]he use of non-human primates should be permitted only in those biomedical areas essential for the benefit of human beings, for which no other alternative replacement methods are yet available.” The law gives particular protection to great apes. Pete Harrison, Great Apes Protected as EU Restrictions Animal Testing, REUTERS, Sept. 8, 2010, [hereinafter: Harrison, Great Apes Protected], available at http://www.reuters.com/article/2010/09/08/us-eu-primates-ban-idUSTRE6873MS20100908; Matej Hruska, EU Tightens up Animal Testing Rules, EU OBSERVER (Aug. 9, 2010), http://euobserver.com/885/30760. In the United States, the Senate recently introduced a bill with the stated purpose of prohibiting “invasive research on great apes and the use of Federal funding of such research.” Great Ape Protection Act of 2010, S. 3694, 111th Cong. §2 (2010), available at http://thomas.loc.gov/cgi-bin/query/z?c111:S.3694:.

28 Jacqueline A. Greff, Regulation of Cosmetics That Are Also Drugs, 51 FOOD & DRUG L.J. 243, 247 (1996).

view exclusively or principally to cleaning them, perfuming them or protecting them in order to keep them in good condition, change their appearance or correct body odours.\textsuperscript{30}

In the United States, the Food and Drug Administration (“FDA”) provides a similar definition for cosmetics:

(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.\textsuperscript{31}

These definitions provide guidance on what types of products might constitute “cosmetics” instead of “drugs.” Under the Cosmetics Directive, categories of cosmetics include skincare, fragrances, makeup, hair products such as shampoos and coloring, deodorants, baby products, shaving products, tanning products, and mouthwashes.\textsuperscript{32} Thus, many products that consumers might consider to be “cosmetics”—for example, face creams, cleansers intended for the purpose of treating skin conditions, and soaps—actually fall within the category of “drugs.” Therefore, corporations may test these products on animals with very little regulation in both the EU and the United States. These definitions are significant because they illustrate the limited scope of Directive 2003/15’s ban on animal testing for cosmetics.

In fact, the definitional disparity between “cosmetics” and “drugs” provides a loophole that cosmetic companies, both in the EU and the United States, may use to their advantage.\textsuperscript{33} The Cosmetics Directive does not explicitly prohibit companies from utilizing animal testing on “dual purpose” ingredients or raw ingredients that go into the cosmetics.\textsuperscript{34} This gray area provides a loophole for cosmetic manufacturers: cosmetic companies could potentially test ingredients on animals under the guise that they are “drug ingredients,” and subsequently include those ingredients in their cosmetic products.\textsuperscript{35} Therefore, some animal-tested ingredients may find their way into cosmetics even after Directive 2003/15 has reached its final stage in

\begin{footnotesize}
\begin{enumerate}
\item Cosmetics Directive, \textit{supra} note 1 (emphasis added).
\end{enumerate}
\end{footnotesize}
2013. This loophole has the potential to undermine the purpose of Directive
2003/15, which is to completely eliminate animal testing in the European
cosmetic industry.36

C. Elements of the Directive: Regulated Conduct

Directive 2003/15 prohibits certain conduct relating to animal testing. The
European Commission targeted three important aspects of animal
testing: 1) the ban on animal testing itself, 2) the ban on marketing and sale
of animal-tested products, and 3) the ban on importation of products that
have been tested on animals or that contain animal-tested ingredients.37

1. The Testing Ban

First, Directive 2003/15 prohibits the testing of final cosmetic products on
animals in EU Member States.38 In issuing Directive 2003/15, the European
Commission reasoned that the safety of finished cosmetic products can be
assessed and assured based on the safety of the ingredients they contain.39
Directive 2003/15 also prohibits testing individual ingredients and
combinations of ingredients on animals.40 This provision is more restrictive
for cosmetic companies. The deadlines by which these tests must end are
outlined in the Commission’s “[t]imetables for the phasing-out of animal
testing,” more fully discussed below.41

2. The Marketing Ban

Second, Directive 2003/15 also targets the marketing of animal-tested
products, stating that “[i]t should be possible to claim on a cosmetic product
that no animal testing was carried out in relation to its development.”42 In
the EU, regulations on cosmetic marketing exist in part to quell concerns
about consumer protection; many consumers want to know whether the
cosmetic companies test their products on animals.

Because Directive 2003/15 addresses testing of both cosmetic ingredients
and final cosmetic products, the marketing ban effectively prohibits the sale
and marketing of any animal-tested cosmetics in the EU.43 This Directive

37 Id.
38 Cosmetics Directive, supra note 1, art. 4a(1)(c).
40 Cosmetics Directive, supra note 1, art. 4a(1)(d).
41 Commission Staff Working Document: Timetables for the Phasing-Out of Animal Testing in the
protects human and animal health through a comprehensive structure that regulates marketing as well as testing. Additionally, cosmetic product packaging may state that the product has not been tested on animals only if both the final product and all ingredients used in it have not been tested on animals. The provision’s aim is to prevent cosmetic companies from misleading consumers. A public outcry against animal testing has partially driven these consumer-based cosmetics regulations.

3. The Importation Ban

Directive 2003/15’s ban on the marketing of animal-tested cosmetic products applies both to imported cosmetic products and those manufactured within Member States. A foreign company cannot import into the EU, or market in the EU, any final product that has been tested on animals, or that contains animal-tested ingredients. This regulation may cause significant barriers to trade in the global cosmetic industry, since the importation ban necessarily requires foreign companies to either comply with EU law or to forego selling their products in EU Member States. Because the importation ban has the potential to create economic difficulties in the United States and implicates world trade rules, the importation ban and U.S. responses will drive this Note’s analysis.

D. Stages of Implementation

The implementation of the animal testing ban takes place in stages. While the European Commission has already implemented several stages of Directive 2003/15, the total ban will take effect in 2013. This Directive requires that the European Commission, in conjunction with the European Centre for the Validation of Alternative Methods (“ECVAM”), “establish timetables of deadlines” that outline the implementation of each facet of the
ban. For instance, Directive 2003/15 requires the Commission to establish timetables for the prohibition of marketing animal-tested cosmetic products for “ingredients or combinations of ingredients which have been tested on animals” and “each test currently carried out using animals.”

A group of experts wrote a report which approximated “the time necessary, including regulatory acceptance, to achieve full replacement of animal testing assuming that optimal conditions were met,” and subsequently prepared the timetables from the information in the report. These experts created the deadlines using an estimate of the time necessary to validate alternatives, albeit under “optimal conditions,” which may not occur in reality. According to the report, “optimal conditions” means that “all necessary resources (technical, human, financial and co-ordination) are met at all times in the process and that the studies undertaken have successful outcomes.” Therefore, a departure from the optimal conditions foreseen in the creation of the deadlines might be a valid basis for derogation or for delaying the deadlines related to the replacement of certain animal tests.

These timetables now represent the mandatory deadlines for EU cosmetic companies. Due to the importation ban, these deadlines also effectively apply to other countries that export cosmetic products to the EU, including the United States. Under the timetables, the Directive has prohibited certain conduct since 2009, including marketing products that have been tested using seven commonly practiced animal tests, while it will only begin to prohibit other conduct, including marketing products that have been tested using an additional eight animal tests, in 2013.

1. Conduct Prohibited as of 2009

For most tests that researchers conduct using animals, the ban on marketing animal-tested cosmetic products became effective on March 11, 2009. However, for some of the tests, the marketing ban will not go into effect until March 11, 2013. In contrast, for all tests included in Directive 2003/15, the testing ban (for both ingredients and final cosmetic products)

---

51 Cosmetics Directive, supra note 1, art. 4(a)(2); see also Timetables, supra note 41, at 4–5.
52 Cosmetics Directive, supra note 1, art. 4(a)(2); see also Timetables, supra note 41, at 2.
53 Timetables, supra note 41, at 2.
54 Id.
55 Id.
56 Id. at 4–5.
57 Id.
58 Timetables, supra note 41, at 4–5.
59 Id.
went into effect in 2009.\textsuperscript{60} This means that while such testing no longer occurs in the EU, cosmetic products may still be sold that include animal-tested ingredients. Nevertheless, as discussed in Part I.B, the animal testing ban does not apply to the “dual purpose” ingredients that may be tested for use in drug products and subsequently included in cosmetic products. As of 2009, Directive 2003/15 prohibits the marketing of cosmetics that have been tested on animals for following seven tests: skin irritancy, phototoxicity (toxicity upon exposure to light), corrosivity, percutaneous absorption (absorption through the skin), genotoxicity (potential to cause genetic mutation and contribute to tumors), ocular irritancy (irritancy to the eyes) and acute toxicity (toxicity occurring within fourteen days of exposure).\textsuperscript{61} Validated alternatives only exist for four of these seven tests.\textsuperscript{62} Concerns exist within the global cosmetic industry about alternatives, as there are “few options when it comes to genotoxicity, ocular irritancy, and acute toxicity.”\textsuperscript{63} If the U.S. cosmetic industry is unprepared with respect to alternative testing methods, it may be difficult to meet the deadlines, especially for these particular tests.

2. Conduct Prohibited in 2013

Upon full implementation in 2013, Directive 2003/15 will prohibit an additional eight tests for the marketing ban.\textsuperscript{64} These tests include “carcinogenicity, photoallergy, cutaneous allergy, toxicokinetics, reprotoxicity, teratogenesis, toxicity—sub chronic and chronic—and photomutagenesis.”\textsuperscript{65} All of these eight tests still require the use of animals, as no validated alternatives are currently available.\textsuperscript{66} These are also some of the most important tests, as they are necessary to determine whether the products are safe for human use. Carcinogenicity tests for cancer-causing properties, and reproductive toxicity tests for negative effects on human reproduction. Due to the importance of these tests in ensuring safety to human health, it is possible that the Commission could grant a derogation (more fully discussed below) even after the final implementation of the ban.

\textsuperscript{60} Id.


\textsuperscript{62} Id. The four tests for which validated alternatives exist are skin irritancy, phototoxicity, corrosivity, and percutaneous absorption.

\textsuperscript{63} Id. (“According to a spokesperson for SkinEthic (a provider of reconstructed human epidermis models that have been validated for skin irritancy and corrosivity), this is due, in part at least, to the industry dragging its feet.”).

\textsuperscript{64} Id.

\textsuperscript{65} Id.

\textsuperscript{66} Timetables, supra note 41, at 5.
3. Use of Alternative Methods and Exceptions

Directive 2003/15 states that “[i]t will gradually become possible to ensure the safety of ingredients used in cosmetic products by using nonanimal alternative methods.”67 In light of this observation, the European Commission went so far as to state that the ban will take effect “regardless of availability of alternative research and testing methods for cosmetics.”68 This provision indicates that the Commission, in its enforcement of Directive 2003/15, will make very few exceptions to the no animal testing rule. However, as mentioned above, there is also a provision allowing for derogations. Directive 2003/15 permits derogations if a human health concern exists. In all likelihood, the lack of alternative testing methods will implicate some human health concerns, since animal tests are used to ensure human safety. Therefore, if alternative research and testing methods are not available when the deadlines come to pass, cosmetic companies may be able to test products on animals to ensure the safety of those ingredients to humans. This would lessen the economic blow to the U.S. cosmetic industry by making compliance with Directive 2003/15 easier. On the other hand, these derogations also provide a loophole for companies to take advantage of the human health exception, thereby allowing them to continue testing on animals. This loophole would hinder the EU’s animal welfare goals significantly.

When the final stage of Directive 2003/15 comes into effect, EU Member States will most likely comply by utilizing new and improved non-animal testing technologies. However, non-animal testing methods may not be available by the final implementation stage, which may lead to derogations and delayed compliance. Some technologies are already in use, while others are still in the research and development process.

Because the ban also concerns products imported into the EU, the cosmetic companies in the United States must react in one of two ways: U.S. cosmetic companies could either 1) challenge Directive 2003/15 under the General Agreement on Tariffs and Trade (“GATT”) or 2) make changes in testing practices in order to continue selling their products in the EU. It is unlikely that a GATT challenge would be successful; however, it is likely that if the World Trade Organization’s Dispute Body upholds Directive 2003/15, the EU would push back the final implementation date to ensure U.S. and other third-party compliance. If a GATT challenge is unsuccessful, U.S. cosmetic companies will most likely adopt technologies already developed and used by EU companies.

---
68 Id. at ¶ 8.
II. CHALLENGES IN THE IMPLEMENTATION OF DIRECTIVE 2003/15

A. Challenges in EU Member States

A number of issues arise concerning the implementation of the Directive 2003/15. First, this Directive allows for exceptions to animal testing in certain circumstances.69 For instance, it creates an exception for testing certain ingredients on animals in the interest of human health.70 This aspect may undermine the general purpose of furthering animal welfare.

1. Exceptions to the Ban on Animal Testing for Cosmetics

Directive 2003/15 states that the EU Member States may grant a derogation if the specific human health problem and the need to test an ingredient on animals is justified.71 The justification must be “supported by a detailed research Protocol proposed as the basis for the evaluation.”72

Under other exemptions in this Directive, researchers may still test products that require testing for toxicity or fertility effects on animals until 2013, even though lawmakers have banned experimenting on animals for the testing of certain other human side effects.73 Additionally, even when the 2013 deadline arrives, lawmakers may push it back if scientists have not found alternative methods for these tests.74 Animal rights groups consider these loopholes unacceptable.75 This contrasts sharply with the cosmetic industry, which believes that the scope of the Directive is too harsh and unfair.76 EU cosmetic companies will likely apply to receive derogations when the final deadline arrives if alternative testing methods are unavailable.


New proposed rules are currently in the negotiations process, which could derail some of Directive 2003/15’s progress.77 The proposed rules would allow Member States to “delay the implementation of alternative testing methods until they are ‘recognised by Community legislation.’”78 This would allow

69 See, e.g., id.
70 Id.
71 Id.
73 Franks, supra note 14.
74 Id.
75 Id.
76 Id.
78 Id.
more leeway for cosmetic companies, making it easier for them to receive a derogation. However, animal rights groups oppose these proposed rules and continue to advocate new standards for testing.\textsuperscript{79} If the Commission accepts all or part of these new proposed regulations, it will be easier for EU and U.S. cosmetic companies to comply with the animal testing ban.

On the other hand, Council Directive 86/609, regarding the protection of animals used for experimental and other scientific purposes, requires that alternative methods replace animal experiments when those methods become available and are scientifically validated, despite economic considerations.\textsuperscript{80} Contrary to the proposed rules, Directive 2003/15 does not currently require community legislation to ensure the widespread use of any particular alternative tests.\textsuperscript{81} Researchers are currently pursuing new, non-animal testing methods. Therefore, as long as science continues to progress in the field of alternative testing, new non-animal tests will continue to replace tests that require live animal subjects. Once scientists have developed and scientifically validated the non-animal tests, Directive 2003/15 mandates their adoption in the EU cosmetic industry with no exceptions.\textsuperscript{82}

3. EU Cosmetic Companies' Preparation for the Ban

In the EU, companies have already prepared for the ban to a certain extent. They have also complied with the portions of the ban already in effect by researching and using alternative methods for cosmetic testing. For example, data from a 2008 EU report on animal testing showed that only France and Spain reported using animals for testing cosmetic ingredients.\textsuperscript{83} France reported testing on over 1,500 animals in 2007 and 2008, while Spain only used twelve animals in 2007.\textsuperscript{84} Additionally, Spain only used rabbits for testing, while France tested products on rabbits, guinea pigs, and other rodents.\textsuperscript{85} France is the only Member State still using a substantial number of animals and performing a large number of animal tests.\textsuperscript{86} The twenty-five other EU Member States reported no animal testing; however, the Commission remains concerned about the accuracy of the reported figures.\textsuperscript{87}

\textsuperscript{79} Montague-Jones, \textit{BUAV}, supra note 33. For example, the British Union for the Abolition of Vivisection ("BUAV") claims that it’s “Humane Cosmetics Standard still has a future,” even after the final stage of the ban is implemented in 2013. \textit{Id.} Due to problems with “dual purpose ingredients,” the BUAV claims its standard (denoted by the “leaping bunny” logo) “remains the only way for consumers to know that their products are cruelty free.” \textit{Id.}

\textsuperscript{80} Directive 86/609, supra note 23.

\textsuperscript{81} See generally Directive 2003/15, supra note 4; see also Directive 86/609, supra note 23.

\textsuperscript{82} See generally Directive 2003/15, supra note 4.

\textsuperscript{83} \textit{Report}, supra note 22, at 4.

\textsuperscript{84} \textit{Id.} No data is available for Spain’s use of animals in 2008. \textit{Id.}

\textsuperscript{85} \textit{Id.}

\textsuperscript{86} \textit{Id.}

\textsuperscript{87} \textit{Id.} at 4, 7.
It is possible that some countries are holding back facts about animal testing in their respective cosmetic industries.

The Commission also stated that although countries continue to make progress, there is still some concern that companies will fail to meet Directive 2003/15’s 2013 deadline. The Commission calls the situation “critical,” stating that the replacement of animal testing methods by validated alternative tests “in relation to complex toxicological endpoints remains scientifically difficult, despite the significant additional efforts that have been launched at various levels.”

Even though the Commission remains skeptical about the elimination of animal testing, the future is not necessarily bleak for animal welfare. Over time, alternative non-animal tests will replace animal tests. A thorough analysis of this situation occurred in the course of the preparation of the study Directive 2003/15 required in 2011, the results of which are not yet available. The situation in the EU can perhaps shed light on how the United States could comply with or challenge the animal testing ban.

**B. Compliance Within the EU: Will the EU Member States be Able to Meet Directive 2003/15’s 2013 Deadline?**

Directive 2003/15 creates serious implications for EU cosmetic companies that are ill-prepared for the ban. These issues and their solutions may lend guidance to U.S. companies in their effort to comply with or challenge the animal testing ban.

1. **General Implications of Directive 2003/15 on EU Cosmetic Companies**

   One of the problems with the scope of Directive 2003/15 is that although it purports to eliminate animal testing entirely by 2013, the Commission has recognized that no alternatives currently exist for certain required tests, including: “repeated-dose toxicity,” “reproductive toxicity,” and “toxicokinetics.” Although virtually every other area of cosmetic product testing utilizes alternative testing methods, the three aforementioned tests still require the use of animals.

   However, under Directive 2003/15, animal testing will end in 2013, regardless of the alternative methods available. This means that EU Member States will have to comply with this directive or challenge it in court.

---


89 *Id.*

90 *Id.*

91 *Id.*


93 *Id.*
States and companies within those states will likely conduct extensive research in the next few years to comply fully with the ban.

2. The Unsuccessful French Challenge to Directive 2003/15

Even though Directive 2003/15 requires compliance regardless of scientifically available alternative testing methods, EU Member States could also apply for a derogation or advance legal challenges. For example, shortly after the Commission enacted Directive 2003/15, France took legal action by filing a challenge with the European Court of Justice. This was a move by the French government to nullify the animal testing ban, since France is home to some of the world’s largest cosmetic companies, including L’Oreal. Cosmetic companies contribute millions of Euros to the French economy each year. As noted above, in 2003, France was one of the few EU Member States that still had an animal testing program. In the case French Republic v. European Parliament and Council of the European Union, France argued that the ban set forth by Directive 2003/15 was too harsh, too ambiguous, incompatible with world trade rules, and harmful to European economic interests.

The French government advanced two main arguments in opposition to the ban. First, they argued that the improvement in animal welfare resulting from Directive 2003/15 would be small. Part of the reasoning underlying this argument relies on the fact that France is one of the few EU Member States that still uses animals in cosmetic testing. Second, the French argued that the ban would likely result in the marketing of cosmetic products that are dangerous or that otherwise have harmful effects on human health. Specifically, the ban could result in the use of alternative testing methods that are not as accurate or effective as animal testing.

In conjunction with the French challenge the European Federation for Cosmetics Ingredients (“EFCI”), an organization that represents seventy cosmetic companies in the EU, brought a simultaneous legal challenge.

94 Osborn & Gentleman, supra note 15.
95 Id.
96 Id.
97 Id.; see also supra Part II(A).
99 Osborn & Gentleman, supra note 15.
100 Id.
101 Id.; see also supra Part II(A).
102 Osborn & Gentleman, supra note 15.
103 Id.
The legal advisor for the British Union for the Abolition of Vivisection ("BUAV"), an animal rights group, described both of these challenges as essentially a conflict between animal welfare and states' economic interest in continuing to test cosmetic products on animals.104

The French challenge was ultimately unsuccessful, as the European Court of Justice upheld Directive 2003/15.105 The Court held that the ban was essential to the accomplishment of the principal goals embodying the Cosmetics Directive (which Directive 2003/15 amended), Directive 86/609, and Directive 93/35, all of which relate to animal welfare in regard to cosmetics.106 The Court rejected the idea that health risks to humans outweighed the benefits of the ban.107 Therefore, based on the opinion resulting from the French challenge, it is unlikely that any other Member States' challenges would be successful unless they can prove to the European Court that real harm to human health will result from the ban. This decision may also be indicative of how the World Trade Organization might rule in relation to a U.S. challenge to Directive 2003/15, as further explored below.

III. CHALLENGES COMPLYING WITH DIRECTIVE 2003/15 IN THE UNITED STATES

A. The Ban on Importation of Animal-Tested Cosmetic Products

The main issue in this Note concerns the ban on importing animal-tested products into the EU. Article 2 of Directive 2003/15 requires that after March 11, 2005, Member States must take all necessary measures to prevent manufacturers and importers within EU Member States from marketing cosmetic products that fail to comply with the animal testing ban.108 This provision makes the Member States and importers liable for cosmetic companies whose products fail to comply with the animal testing ban, regardless of the company's location. In other words, importers must actively investigate the practices of companies that wish to import their products into the EU and ensure that no company imports animal-tested products.

B. Consequences of the Importation Ban in the United States

Due to the importation ban, the deadlines set forth by Directive 2003/15 also effectively apply to other countries that wish to export cosmetic products.
to the EU, including the United States. This may have serious and far-reaching consequences outside the EU, especially in the United States. While cosmetic companies in the EU have already begun researching alternative testing methods in light of the ban, many U.S. companies have yet to realize the full scope of the ban’s implications. In the United States, the use of alternative testing methods for cosmetics is not as prevalent, primarily due to a lack of legislation on the issue. This lack of legislation is largely due to self-regulation of the cosmetic industry in the United States. For example, the U.S. cosmetic industry employs no measures to limit the number of laboratory animals used. Even though final cosmetic products do not always require testing (similar to the EU), cosmetic companies test most of the ingredients used in the formulation of their products on animals. The only U.S. regulation occurs through self-regulation by cosmetic companies. In an effort to appear more environmentally conscious and animal friendly to consumers, some cosmetic companies have stopped testing on animals. For example, many companies have adopted the BUAV’s “leaping bunny” logo, which denotes that a product is “cruelty-free.”

The ban on animal-tested cosmetic products has the potential to cause trade problems with the United States, which exports a large percentage of its cosmetics to the EU. In today’s global cosmetic market, U.S. cosmetic companies depend on profits from products sold in European markets. This dependence will inevitably require U.S. companies to either challenge Directive 2003/15 or pursue more aggressive non-animal alternatives for product and ingredient testing. According to the Cosmetics, Toiletries, and Fragrance Association (“CTFA”), “the European Union is a $43 million cosmetic market.” The U.S. cosmetic industry’s dependence on such a large market indicates the level of economic hardship that could result from an inability of U.S. cosmetic companies to sell their products in the EU market.

However, the U.S. cosmetic industry has made little progress in the implementation of alternative testing methods, making it difficult for many cosmetic manufacturers to comply with Directive 2003/15 by 2013. Therefore, it is possible that the United States will challenge the Directive under world trade rules because the inability to sell any cosmetics in the EU could be

109 See id.; see also Timetables, supra note 41.
113 EU Bans Cosmetic Testing on Animals, supra note 111.
114 Id.
devastating to U.S. cosmetic companies. If such a challenge is unsuccessful, the U.S. cosmetic companies must find another approach to complying with the ban.

C. Possible U.S. Responses to the Importation Ban

Outside the EU, Directive 2003/15 could have potentially devastating effects on cosmetic manufacturers that do not comply with the ban because it prohibits EU Member States from importing all animal-tested cosmetic products.115 U.S. cosmetic companies could respond to the importation ban in several ways. First, the United States could challenge Directive 2003/15 under GATT.116 Second, if the challenge under GATT rules proves unsuccessful, U.S. cosmetic companies could attempt to comply by developing and using non-animal testing methods. These two options are the most likely courses of action for the United States because they would ensure compliance with EU law, either by bypassing the directive with a GATT challenge or by using alternative testing methods to comply with the ban. However, if both of these options prove to be unfeasible or impractical, the United States could pursue other options. For example, U.S. cosmetic companies could take one of the following courses of action: make separate product lines for EU and other markets, raise prices on cosmetics to make up for economic losses in the EU, or seek out new markets in which U.S. companies could sell their products. This Note will focus primarily on the first two options.

1. Legal Challenge Under the GATT

In order to challenge Directive 2003/15, the United States could file a complaint under the GATT.117 While the GATT rules have been highly criticized by proponents of animal welfare,118 these rules do provide means for invalidating animal welfare laws on the ground that they violate world trade rules. The GATT prohibits favorable treatment for domestic products over imported “like” goods—favoring one country’s products over another’s.119 It includes limited exceptions for important interests.120 Under these rules,

117 GATT 1947, supra note 116.
118 For example, the Compassion in World Farming Trust criticizes the WTO, stating that the free-trade rules “have been wrecking progress on animal welfare.” COMPASSION IN WORLD FARMING TRUST, WTO: THE GREATEST THREAT FACING ANIMAL PROTECTION TODAY at 2, available at http://www.ciwf.org.uk/includes/documents/cm_docs/2008/w/wto_the_greatest_threat.pdf (urging that the WTO rules should be changed to better accommodate animal rights laws).
119 GATT 1947, supra note 116.
120 GATT 1947, supra note 116, arts. I, III, & XX; see also Jody M. Endres, Clearing the Air: The Meta-Standard Approach to Ensuring Biofuels Environmental and Social Sustainability, 28 Va.
the GATT states that if a contracting party believes a benefit owed to it has been impaired by another contracting party, the contracting party may “make written representations or proposals to the other contracting party or parties which it considers to be concerned” in the dispute.\textsuperscript{121} In this case, the United States could petition the European Parliament and Council under the GATT Articles I and III.

Additionally, under the GATT rules, any contracting party to the WTO and the GATT must give full consideration to the opposing party’s representations or proposals.\textsuperscript{122} Therefore, under the rules, the EU would have to consider the United States’ position in good faith and make a determination on the merits of the petition. It is also possible (if the consultations between the EU and the United States do not prove to be fruitful) that a WTO committee could hear the case.\textsuperscript{123}

As previously mentioned, the general rule under the GATT is that contracting parties cannot show preference for domestic products over “like” imported products.\textsuperscript{124} Article I, section 1 of the GATT states that “any advantage, favour, privilege or immunity granted . . . to any product originating in or destined for any other country shall be accorded immediately and unconditionally to the like product originating in or destined for the territories of all other contracting parties.”\textsuperscript{125}

Article III also states that:

\begin{quote}
The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favourable 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.\textsuperscript{126}
\end{quote}

The GATT rules prohibit a preference for domestic products over imported products.\textsuperscript{127} Directive 2003/15 effectively bans the sale of foreign products in the EU if they do not meet the animal testing requirements. In

\textsuperscript{121} GATT 1947, \textit{supra} note 116, art. XXIII, § 1.

\textsuperscript{122} Id.

\textsuperscript{123} Id. art. XXIII, § 2.

\textsuperscript{124} Id. arts. I, III.

\textsuperscript{125} Id. art. I, § 1 (emphasis added).

\textsuperscript{126} GATT 1947, \textit{supra} note 116, art. III, § 4.

\textsuperscript{127} Id.
application, Directive 2003/15 gives preference to domestic (non-animal-tested) products over foreign (potentially animal-tested) products.

Under the GATT, analysis of Directive 2003/15 would consist of three separate questions. The three questions to determine whether the ban violates GATT are: 1) does Directive 2003/15 give an “[a]dvantage, favour, privilege or immunity” to domestic over foreign products? 2) does it regulate products “[o]riginating in or destined for any other country”? and, finally, 3) does it regulate “like” products?\footnote{\textsuperscript{128}}

The first part of the GATT analysis asks whether Directive 2003/15 assigns an “[a]dvantage, favour, privilege or immunity.”\footnote{\textsuperscript{129}} In the present case, the advantage at stake is other countries’—such as the United States—ability to sell cosmetic products within the territories of EU Member States. As previously discussed, the importation ban grants the privilege only to cosmetics that have not been tested on animals; in many countries, the use of non-animal alternative testing methods might be too expensive or not feasible at all.

The second part of the GATT analysis asks whether the products in question are “[o]riginating in or destined for any other country.”\footnote{\textsuperscript{130}} Here, the products at issue originate in a different country than the one issuing the law. The EU has promulgated the law, and the United States (among other countries) wishes to sell its products within the EU Member States’ territories.

The third part of the GATT analysis asks whether the law restricts the trade of “like” products.\footnote{\textsuperscript{131}} Directive 2003/15 bans products that are virtually identical to products that it allows—the products may contain identical ingredients, yet one is given preference because it has not been tested on animals. This could be especially true in the case of global cosmetic companies, which manufacture products in many different countries and under different laws. The only difference between the products would be that EU-made cosmetics are tested using non-animal alternative methods, while cosmetic products manufactured elsewhere were potentially tested on animals.

When a country bans certain goods in furtherance of animal welfare protection, “the measure will most likely be in violation of the substantive obligations in GATT Articles I and III.”\footnote{\textsuperscript{132}} However, Article XX of the GATT

\textsuperscript{128} Id.
\textsuperscript{129} Id. art. I.
\textsuperscript{130} Id.
\textsuperscript{131} GATT 1947, supra note 116.
\textsuperscript{132} Dr. Laura Nielsen, \textit{The WTO & Animal Welfare: “Sufficient Nexus” for Morally Based NPR-PPMs in GATT Article XX?}, in \textit{ACADEMIC ONLINE MAGAZINE OF THE EUROPEAN LAW STUDENTS’ ASSOCIATION: SELECTED PAPERS ON EUROPEAN LAW} 3, 3 (2004), available at
provides that even if products are “like” and therefore subject to challenges under Articles I, III, or X, the importing nation may nonetheless assert a human or animal health exception. In the case of cosmetics, both human and animal health concerns are at stake, albeit on opposite sides of the issue. Directive 2003/15 promotes animal health, while opponents of the ban argue that it compromises human health concerns. Since both animal and human health are important concerns, a complete analysis of Directive 2003/15 under the GATT will likely require a balancing approach of human versus animal concerns.

The primary goal or objective of Directive 2003/15 is to protect animal welfare by severely restricting the number of animals used for testing purposes and eliminating animal testing for cosmetics altogether. However, legitimate human health concerns also exist, especially if viable and validated alternative testing methods are not yet available in the United States by the time the ban comes into full effect in 2013. U.S. compliance with the ban without first establishing adequate alternative testing methods could result in the creation of dangerous cosmetic products, thereby placing human consumers in danger of suffering adverse effects. The human health concerns implicated by the ban would not be permanent, however, since the creation and validation of alternative methods for the cosmetic tests in question would eventually eliminate any negative human health effects. For this reason, it is unlikely that the WTO would invalidate Directive 2003/15 altogether; rather, a “successful” challenge for U.S. cosmetic companies would likely result in merely pushing back the final implementation date.

Additionally, positive effects of alternative testing methods might also be taken into account. It is possible that alternative testing methods will yield more accurate and safe results. The Humane Society International (“Humane Society”) contends that “most animal tests have never been properly validated to demonstrate their relevance to humans, and as a result may under- or over-estimate real-world hazards to people.” For example, the Humane Society notes that animal tests “failed to predict the birth defect-causing properties [of] PCBs, industrial solvents and many drugs, while cancer tests in rats and mice failed to detect the hazards of asbestos, benzene, cigarette smoke, and many other substances.” In some cases, the failure of these tests to detect dangers to human health pushed back “consumer and worker protection measures by decades.” As explained below, several non-
animal alternative testing methods exist which might provide better indicators of cosmetics’ effects on humans.

In conclusion, taking human and animal health concerns into consideration, the U.S. challenge under the GATT rules might prevail, since the three-step GATT analysis disfavors countries that provide advantages to their products over similar imported products. The success of the U.S. challenge depends on whether the WTO deems human health concerns sufficiently pressing. However, even if the Commission ultimately upholds Directive 2003/15, the Commission could still delay final implementation of the animal testing ban. This would ensure that other non-EU countries have enough time to develop or adopt alternative technologies in order to increase compliance with the ban.

2. Pending Canadian Challenge to the EU Ban on the Sale and Marketing of Seal Products

Canada recently launched a challenge under the GATT rules that may shed some light on the potential U.S. challenge to the ban. In 2009, the European Parliament and Council passed Regulation 1007/2009 on Trade in Seal Products (“the Regulation”) that banned the sale and marketing of seal products in the EU. The law prohibits anyone from placing seal products on the market unless those products come from traditional hunts done by indigenous communities. Although the ban exempts indigenous peoples, the indigenous population contends that the ban caused the price of seal pelts to collapse. The law went into effect on August 10, 2010, but Canada had already challenged the law prior to its implementation.

Canada challenged the Regulation at the European Court of Justice, which upheld the law on the grounds that it would not overburden indigenous communities financially. On the other hand, the GATT challenge remains unresolved and is currently in the consultations process.

---


140 Id. art. III, § 1.


144 Request for Consultations by Canada, supra note 138.
Canada made its GATT challenge under Article XX, under which the WTO will weigh whether financial concerns of indigenous peoples in Canada outweigh animal health concerns. If the European Court of Justice decision bears any indication as to how the GATT challenge will be decided, Canada is unlikely to prevail. However, under the GATT, the WTO is likely to analyze restrictions on trade more stringently given the language of Articles I and II, which strictly prohibit barriers to trade.

It will be interesting to see whether Canada prevails on this challenge, as it appears that the indigenous peoples have a strong interest in maintaining the seal trade. Nonetheless, even if Canada loses, there is still one major difference between Canada’s challenge and the potential U.S. challenge: while Canada relies only on human financial interests, the United States could argue that the Directive harms human health interests. This could prove to be an important argument for the United States, as it may sway the WTO in its favor. Additionally, Canada is currently looking for new markets in light of the ban, most notably in China. The United States may wish to follow Canada’s example in searching for new markets if its GATT challenge is unsuccessful and if alternative testing methods are too costly.

3. Alternative Means of Compliance if the U.S. GATT Challenge Proves Unsuccessful

In the event that the U.S. challenge to Directive 2003/15 under the GATT rules falls short, U.S. cosmetic companies will need to comply in other ways. Outside the EU, the ban could have potentially devastating effects on cosmetic manufacturers that do not comply with it, as it will prohibit EU Member States from importing animal-tested products. The Coalition for Consumer Information on Cosmetics notes that in the modern global economy, U.S. cosmetic companies “depend on profits from their European markets.” Without a doubt, if the GATT challenge is unsuccessful, dependence on EU markets will require U.S. cosmetic companies to “more aggressively pursue non-animal alternatives for product testing.”

In the United States, Congress has not promulgated any legislation comparable to the EU Cosmetics Directive with respect to animal testing. Nonetheless, manufacturers should take several steps to eliminate animal testing from their cosmetic products. Despite the difficulties with certain toxicology tests discussed above, U.S. cosmetic manufacturers should start

---

145 As previously noted, article XX provides for limited exceptions to the general rule against trade barriers, including human and animal health. GATT 1947, supra note 116, art. XX.
146 Id. arts. I & II.
147 Mortished, supra note 141.
149 Id.
implementing other alternative testing methods to comply with Directive 2003/15, thereby maintaining the ability to sell cosmetic products in the EU. An attempt by U.S. cosmetic companies to comply with the ban would probably be a sound economic strategy, since those companies depend on the EU market for profits.

The U.S. Humane Society argues that some alternative testing methods including “EpiSkin, EpiDerm and SkinEthic—each composed of artificial human skin—can save thousands of rabbits each year from painful skin corrosion and irritation tests.”150 Other tests, which would replace the Draize eye irritancy test—in which ingredients are repeatedly injected into live test animals’ eyes—are the “Bovine Corneal Opacity and Permeability Test” and the “Isolated Chicken Eye Test.”151 These use “eyes from animals slaughtered for the meat industry” instead of live test animals to analyze ingredients which may irritate human eyes.152 These alternative testing methods, if implemented on a larger scale by cosmetic companies, could spare many laboratory animals by making live-animal tests unnecessary.

D. Recommendations on a Course of Action in the United States

It might be in the United States’ best economic interests to challenge Directive 2003/15 under the GATT rules, if only to push back the deadlines to ensure that U.S. cosmetic companies have enough time to implement alternative testing methods. However, based on the European Court of Justice decisions on Directive 2003/15 and the seal ban in Canada, success in the WTO is unlikely. Therefore, EU and U.S. cosmetic companies should adopt non-animal alternative testing methods as they become available, and should conduct research to discover additional alternative testing methods. Making the change to the few alternative testing methods noted above could save many laboratory animals from painful and potentially deadly tests. While not discussed in this note, a variety of other alternative testing methods currently exist, which U.S. cosmetic companies should utilize.153 A few changes could save the lives of many animals and would not overburden cosmetic companies, especially in the United States, where the technology is available. The use of alternative testing methods would not only be a good ethical choice, it would also ensure the future economic success of U.S. cosmetic companies through continued access to EU markets.

151 Id.
152 Id.
IV. CONCLUSIONS

Directive 2003/15 is sweeping in its scope. It drastically restricts the ability of cosmetic companies to test products on animals and requires them to spend money and time finding alternative testing methods to ensure continued product safety. Although some Member States may have difficulties meeting the animal testing ban’s requirements by 2013, it is unlikely that a legal challenge in the EU would be successful because the human health concerns do not outweigh the benefit to animal safety.

In the United States, a legal challenge is unlikely to succeed as well. If the United States brought a GATT challenge against Directive 2003/15, there is a small chance that it would succeed depending on how much weight the WTO gives to animal health concerns versus possible human health concerns. The WTO would also address the issue of whether or to what extent these human health concerns exist. Even if the Commission does not invalidate Directive 2003/15 or find it a violation of its GATT rules, there is a chance that the Commission would postpone its final implementation. On the other hand, if the GATT challenge is entirely unsuccessful for the United States, cosmetic companies will need to develop alternative technologies. In that case, since many EU companies have already developed new alternative testing technologies, it is likely that U.S. companies would utilize these same testing methods to replace animal tests. In conclusion, given the harm animals suffer at the hands of cosmetic companies combined with the low probability of a successful GATT challenge to Directive 2003/15, adopting alternative testing methods and ending live-animal tests is a morally and economically sound change for EU and U.S. cosmetic companies.