

# EU Sales Ban on New Cosmetics Tested on Animals: Impact on Alternative Methods, WTO Implications and Animal Welfare Aspects

Irmela W. Ruhdel

*Animal Welfare Academy/Akademie für Tierschutz, Spechtstrasse 1, 85579 Neubiberg, Germany*  
E-mail: [irmela.ruhdel@tierschutzakademie.de](mailto:irmela.ruhdel@tierschutzakademie.de)

**Summary** — In 1993, the European Union (EU) adopted *Directive 93/35/EEC*, calling for a sales ban on new cosmetic products containing ingredients tested on animals after 1 January, 1998, provided that alternative methods had been developed by then. In May 2000, for the second time, the European Commission postponed that ban. The Commission justified the repeated postponement of the sales ban by saying that no animal-free methods were available, although three *in vitro* methods were scientifically approved in 1997. With three years delay, these methods have been published and therefore “made available” in the EU. OECD acceptance is still awaited. Another reason for the postponement was the fear of possible World Trade Organisation (WTO) conflicts. However, according to WTO rules, the protection of public morality or animal health could justify a restriction of the free trade principle. From the animal welfare point of view, an unqualified EU sales ban, combined with an animal testing ban, would provide the incentive to further promote the development and acceptance of alternative methods and to prove that ethical standards are legitimate concerns under WTO rules.

**Key words:** *alternative methods, animal experiments, animal testing ban, animal welfare, cosmetic marketing ban/sales ban, EU legislation, validation, World Trade Organisation.*

## Background Information

In the European Union (EU), *Council Directive 76/768/EEC* on the approximation of the laws of the Member States relating to cosmetic products regulates the safety of cosmetic and personal care products. Article 2 of this Directive states that no product may be sold that would cause damage to human health under normal or reasonable conditions of use. The Directive does not require any animal tests for the safety assessment of finished cosmetic products. Furthermore, in 1997, the European Commission (EC) explicitly announced that, for the general evaluation of finished products, animal experiments are not necessary, but that their safety can be assessed using the knowledge of the toxicological profile of the ingredients of the product and by performing *in vitro* testing methods (1).

New cosmetic ingredients, however, are treated as any other chemical substance. Thus they have to be registered according to the Dangerous Substances Directive, *Directive 67/548/EEC* (on classification, packaging and labelling of dangerous substances). Annex V of this Directive lists tests for the safety assessment of chemicals, including a number of toxicological animal experiments that are in line with respective OECD guidelines for the testing of chemicals.

Therefore, current endeavours to set an end to animal experiments for the testing of cosmetics

address the toxicity testing of new cosmetic ingredients.

The key elements to achieve a legal abolition of animal testing for cosmetics are the “marketing or sales ban” and the “animal testing ban”. For a better understanding of the demands of the animal welfare movement in regard to the EU cosmetics policy, the meaning and the consequences of these two key elements have to be kept in mind:

1. A *marketing or sales ban* on new cosmetics tested on animals would mean that no cosmetic product or ingredient could be marketed within the EU that has been developed and tested in animals anywhere in the world. Thus, a cosmetic product containing an ingredient tested on animals could also no longer be marketed in the EU. The marketing ban would still enable European companies to conduct animal experiments, even in the EU, provided that the product would be marketed in countries outside the EU.
2. An *animal testing ban* in the field of cosmetics would only affect manufacturers of cosmetics and cosmetic ingredients in the EU. With an animal testing ban, it would become prohibited to perform animal experiments for the testing of cosmetic ingredients and products on the territory of the EU. The animal testing ban alone would have no effects on animal testing outside

the EU: new cosmetic products or their ingredients tested on animals elsewhere could continue to be sold within the EU indefinitely.

It must be kept in mind that any ban would only apply to new cosmetic products and ingredients. All the thousands of cosmetic products and approximately 8000 cosmetic ingredients that are already on the market would not be affected.

### **Position of European Animal Welfare Organisations**

Animal welfare organisations, such as the German Animal Welfare Federation and its European umbrella organisations, Eurogroup for Animal Welfare and the European Coalition to End Animal Experiments, want to see an end to all animal experiments performed for the testing of cosmetic products and ingredients. We are therefore calling for an immediate and unconditional sales ban on new cosmetic products tested on animals and on cosmetic products containing ingredients tested on animals. Additionally, we are calling for an immediate ban on animal testing of ingredients and finished cosmetic products within the EU. According to our opinion, these bans should come into force, regardless of the availability of animal-free test methods.

With regard to the economic impact of these two key requests, it must be kept in mind that a huge number of cosmetic products are already on the market, sufficient to last a life-time, and certainly sufficient to last until further non-animal test methods have been developed. Until then, the industry can continue to develop and sell new, innovative and safe cosmetic products involving the more than 8000 well-known ingredients that already exist.

Animal welfare organisations do not consider it ethically acceptable for animals to continue to suffer and die for the development of new cosmetics (2). These demands are backed up by a huge majority of EU citizens, as could be demonstrated through opinion polls and petitions (e.g. 3–5).

### **Current Developments in the EU Toward a Legal Basis for the Abolition of Animal Experiments for Cosmetics**

#### **The Sixth Amendment to the EU Cosmetics Directive**

In 1993, as a result of strong and long-standing pressure from animal welfare organisations, EU citizens and the European Parliament, the EU adopted a ban on the marketing of cosmetics con-

taining ingredients and combinations of ingredients tested on animals to come into force after 1 January 1998. However, the corresponding Directive (*Council Directive 93/35/EEC*), amending for the sixth time the Cosmetics Directive, *Directive 76/768/EEC*, laid down that this date could be postponed if in the meantime there had been insufficient progress in developing satisfactory methods to replace animal testing and, in particular, if alternative methods of testing would not have been scientifically validated.

And this was exactly what happened. In 1997, the EC postponed the marketing ban for the first time until the year 2000 (*Commission Directive 97/18/EC*). This delay was justified by claiming that there had not been sufficient progress in developing and accepting non-animal testing methods. Additionally, the EC argued that a marketing ban on new cosmetics tested on animals from Third World countries might conflict with the rules of the World Trade Organisation (WTO). In May 2000, the date of the marketing ban was delayed for a second time, until June 2002 (*Commission Directive 2000/41/EC*), with the same arguments, and despite the fact that in the meantime at least in two areas of safety assessment non-animal test methods had been officially accepted at the EU level.

Two years ago, in parallel to the repeated postponement of the marketing ban called for in the Sixth Amendment to the Cosmetics Directive, the EU has initiated the Seventh Amendment to the Cosmetics Directive. For this reason, the date of June 2002 has now elapsed without bringing into force any marketing ban.

#### **Proposals for the Seventh Amendment to the EU Cosmetics Directive**

In April 2000, the EC published a draft for a Seventh Amendment to the EU Cosmetics Directive, *COM(2000) 189 final*. In this draft, it was proposed to repeal the marketing ban on new cosmetics tested on animals and to replace it with an EU animal testing ban for cosmetics. Obviously, the EC is trying to avoid any possible conflicts with WTO rules. However, as has become clear from the implications of the two different bans, from the animal welfare point of view, a testing ban alone is not at all acceptable. It would merely result in animal testing being moved to countries outside the EU, thus simply exporting the problem, while any new product tested on animals outside the EU could continue to be sold within the EU indefinitely.

According to EU legislative procedures, the adoption of the Seventh Amendment to the EU Cosmetics Directive is a so-called “co-decision procedure”. This means that the EC draft needs to be approved both by the European Parliament and by

the Council of Ministers. However, at the first reading, the Parliament rejected the Commission's proposal and asked for a marketing ban of finished cosmetics products tested on animals and of cosmetics products containing ingredients tested on animals five years after adoption of the Directive, combined with an unconditional animal testing ban for cosmetics within the EU (COM[2000] 189-C5-0244/2000 – 2000/0077/[COD]).

In response to this, the Council of Ministers published a compromise proposal (15073/1/2001 – C5-0072/2002), the so-called "common position" that once again failed the demands of the EU citizens and widely ignored the Parliament's proposal. Although the compromise proposal contained a marketing ban for new cosmetics tested on animals and the animal testing ban, both bans had been made conditional upon the OECD respecting acceptance of alternative methods by the EU.

At the beginning of 2002, this compromise proposal went to the Parliament for the second reading. Once again, the Parliament backed up its strong demands for an animal testing ban as of 2005 and a marketing ban to come into force five years after the adoption of the Directive. Being pressured to accept that insisting on a complete marketing ban could lead to an overall failure of the Seventh Amendment, the Parliament agreed on the compromise to postpone the marketing ban in regard to three endpoints of safety testing — repeated-dose toxicity, reproductive toxicity and toxicokinetics, thus having it come into force no later than ten years after the adoption of the Directive.

Currently, a conciliation procedure is taking place, which means that a compromise text is being negotiated by representatives from both the Council of Ministers and the European Parliament. The joint compromise text will pass to the Parliament for a third reading and simultaneously to the Council of Ministers for its consideration. If both bodies agree to the joint text, the Council of Ministers will adopt the Directive, but if either rejects it, the proposal will lapse. The final decision is expected in the very near future.

Animal welfare organisations are concerned that the joint compromise text will contain further restrictions of the bans or additional exceptions, which would render the bans meaningless.

### **The Impact of the Announced Marketing Ban on the Development and Acceptance of Animal-free Methods**

The marketing ban announced in 1993 was a strong incentive for the EC and the European cosmetics industry to promote the development and acceptance of animal-free methods. The European Centre for the Validation of Alternative Methods (ECVAM)

chose the replacement of animal testing for cosmetics as one of its priority areas for action. In 1995, ECVAM organised an initial workshop on the development and validation of non-animal tests and testing strategies for the identification of a coordinated response to the challenge and the opportunities presented by the Sixth Amendment to the Cosmetics Directive (6). As a follow-up to this workshop, several other workshops (e.g. 7–10) and validation studies took place under the auspices of ECVAM (e.g. 11–14). Similarly, the European cosmetics industry allocated substantial financial and personal resources to the development and validation of animal-free methods (e.g. 15, 16).

In spite of these efforts, from the animal welfare point of view, progress has been extremely slow. Despite the excellent work done by ECVAM, until now, only three animal-free test methods have been formally validated. It took seven years for the successful validation of an animal-free method for the assessment of the phototoxic potential of chemicals and five years to finalise the validation of two methods for the *in vitro* testing of skin corrosivity.

Many obstacles had to be surmounted. First, a proper validation procedure had to be established and approved, and there were uncertainties on how to decide that an alternative method was "scientifically validated". For example, in November 1996, ECVAM stated that the *in vitro* 3T3 NRU (neutral red uptake) phototoxicity test could be considered a reliable and reproducible method (17). Nevertheless, the Scientific Committee on Cosmetology and Non-Food Products (SCCNFP) of the European Commission asked for an additional study with 10 to 15 chemicals that delayed the finalisation of the validation study for more than a year (14, 18).

A major obstacle to the successful performance of validation studies was, and still is, the availability of reliable and reproducible data with which to compare the results of a new method. In general, the validity of an alternative method is evaluated against the results from the animal test that it is intended to replace. The *in vitro* phototoxicity test almost failed in its validation study, because one test substance, Piroxicam, had been classified to be phototoxic according to the animal test data. In the *in vitro* test, no phototoxic effect could be determined; therefore, this *in vitro* test result was considered to be a false negative (19). Since it is much worse if a new test method cannot recognise a potential hazard than if it recognises a hazard that does not exist, chances were low that the *in vitro* test would ever become accepted. In the end, however, human data showed that the *in vitro* test result was correct and that it was the animal test result that was false.

Another example is the outcome of previous validation studies for eye irritation testing. One of the main reasons that they failed is that the results gained

from the Draize eye irritation test on rabbits are of such poor quality (6, 15, 20, 21). These examples clearly demonstrate that major problems that arise during the validation of alternative methods are caused by defaults of animal experiments. Thus, animal experiments impede their own replacement. It would go beyond the scope of this presentation to discuss in depth the problems related to the current strategy to compare the results of a newly developed *in vitro* test method with the results of the animal test that the new test is intended to replace. It will suffice to state that this is an attempt that is due to fail if the starting point itself is unreliable and not reproducible.

A further argument of the EC for postponing the marketing ban in 1997 and 2000 was the fact that none of the new animal-free methods had been adopted as OECD guidelines for the testing of chemicals at that time. However, not only is the validation process itself time-consuming, but the process for a scientifically approved method to become officially accepted is too lengthy. It took more than two years for the validated *in vitro* methods for phototoxicity and skin corrosivity to become officially accepted in the EU by being included in Annex V of the Dangerous Substances Directive (*Directive 2000/33/EC*). The *in vitro* tests became legally binding in the EU in June 2000. However, the acceptance of these methods on OECD level is still awaited. In May 2002, the draft guidelines were agreed at a WNT-OECD meeting, so that, hopefully, these tests will be incorporated into the OECD testing guidelines for the testing of chemicals in the near future.

It is expected that, in the short to medium term, it will also become possible to replace animal experiments in other fields of safety testing, such as eye irritation, skin sensitisation or acute systemic toxicity testing (22). However, bans that are dependent on the EU or even OECD acceptance of the available animal-free methods will mean that animal experiments for cosmetics will continue to be conducted for years to come.

One problem that we are currently facing is that the EC no longer grants a high priority to endeavours to replace animal experiments for cosmetics. It is argued that only 0.35% of all animal experiments are performed for the testing of cosmetics (e.g. 23). The cosmetics industry has also diminished efforts to develop animal-free testing methods, complaining that animal-free methods developed for cosmetics can also be used to test other chemical substances and that they do not want to carry the entire burden (e.g. 23). It goes undisputed that the purpose of a newly developed toxicity test method cannot be restricted to the testing of a certain type of product. The successful development of a new animal-free method in the field of cosmetics will have animal welfare implications that far exceed the issue of cosmetics testing. Therefore, joint efforts by all the relevant industrial

sectors are to be recommended. Additionally, it is hoped that the current developments related to the new EU chemicals policy to promote the development and acceptance of new non-animal test methods would be advantageous for the abolition of animal testing in the field of cosmetics.

### **WTO Implications of a Possible Marketing Ban on New Cosmetic Products Tested on Animals**

Repeatedly, the EC has expressed its fear that an EU marketing ban of new cosmetics tested on animals would not be WTO-compatible. In the following paragraphs, this concern is addressed by discussing WTO regulations relevant for a possible marketing ban.

Article III (4) of the WTO/GATT rules (*General Agreements on Tariff and Trade, 1947 and 1994*) states that products imported from another WTO member country must not be treated less favourably than "like" (similar) nationally manufactured products.

Therefore, the two crucial questions are whether cosmetic products tested in animal experiments are similar to those products that were manufactured without animal experiments. In addition, it must be checked whether a marketing ban privileges cosmetic products manufactured in the EU to those produced in non-EU countries.

With regard to the question of similarity, it is sometimes said that their process of production cannot define products. It is said that, since one cannot see whether a finished cosmetic product or its ingredients were tested on animals, one cannot differentiate between differently manufactured cosmetics. However, so far, such a narrow interpretation of this article has not been officially acknowledged by the WTO. On the contrary, in 1970, the WTO Working Party on Border Tax Adjustments indicated that it would be decided on a case-by-case basis, whether imported and nationally manufactured products are to be regarded as "similar products". The Working Party stated that the "taste or the habit of the consumers, that differ from country to country" have to be taken into account for this distinction.

As numerous opinion polls and petitions show, European consumers want to differentiate between cosmetics on the basis of their "animal friendliness". Therefore, it is quite realistic to assume that the WTO would accept the habit of a vast majority of the European consumers as a relevant criterion, and imported cosmetics that were developed with animal experiments could therefore be regarded as "not similar" products.

Beyond that, a marketing ban on cosmetics tested in animal experiments would not serve to give privileges to the domestic production. Instead, this ban

would impose stricter regulations on EU manufacturers. In 1992, during the WTO controversy on alcoholic beverages in the USA, it was stated that Article III was not intended to prevent parties from adopting measures that serve purposes other than the protection of the domestic products.

Thus, it is far from evident that Article III of the GATT regulations would stand in contradiction to an EU marketing ban for cosmetics tested on animals. On the contrary, this Article might even be a suitable means to justify this very same marketing ban at the level of the WTO.

In addition, Article XX of the GATT regulations can be used to defend the marketing ban. This Article allows for exceptions to the WTO rules aimed at protecting public morals (XXa), and aimed at protecting the life or health of human beings, animals or plants (XXb).

The suffering and death of animals for economic reasons poses a serious moral conflict for many citizens of the EU. It can, therefore, be considered to be an offence against good customs and public morals, if animals have to endure pain and are killed to bring new cosmetics on the market. An EU-wide marketing ban on new cosmetics tested in animal experiments could therefore be justified on the basis of Article XXa of the GATT.

Article XXb also supplies a basis for defending a marketing ban. Animal experiments go along with suffering, pain and damage for the animals. Thus, the health and the life of thousands of experimental animals are at risk, regardless of whether the animal experiments are conducted outside or within the EU. A marketing ban would therefore prevent unnecessary experiments on animals, and thus, protect the animals' health and life.

Likewise, exceptional measures, which are covered by Article XX, must not privilege domestic production. As already mentioned above, the marketing ban does not selectively affect manufacturers from non-EU countries, but also manufacturers in the EU.

A recent case proves that a marketing ban can indeed be defended under the WTO rules. In December 2000, the USA issued a law on the prohibition of the import of products made with dog or cat fur and the prohibition to sell them in the USA (*Prohibitions on the Importation of products made with Dog or Cat Fur, 2000*). During the legislative procedure, the US-responsible persons for trade came to the conclusion that this measure did stand in agreement with international obligations, including those of the WTO.

The US Congress is therefore of the opinion that the exceptions laid down in Article XX of the GATT apply to non-discriminating animal welfare measures. The following statements were made:

*(7) The trade of dog and cat fur products is ethically and aesthetically abhorrent to United States citizens . . .*

*(9) The imposition of a ban on the sale, manufacture, offer for sale, transportation, and distribution of dog and cat fur products, regardless of their source, is consistent with the international obligations of the United States because it applies equally to domestic and foreign producers and avoids any discrimination among foreign sources of competing products. Such a ban is also consistent with provisions of international agreements to which the United States is a party that expressly allow for measures designed to protect the health and welfare of animals . . .*

It can be concluded that an EU-wide marketing ban on cosmetics tested in animals would have a realistic chance of being successfully defended at the level of a WTO panel. At present, it is not clear whether an EU-wide marketing ban would be contested at all. The USA is repeatedly mentioned as a potential plaintiff. However, as demonstrated above, in December 2000, the USA issued an import and sales ban on cat and dog fur products, amongst other reasons, for animal welfare purposes.

## Conclusions

Nine years after the announcement of an EU-wide marketing ban in the European Cosmetics Directive, we still do not have a marketing ban for animal-tested finished cosmetics products. Likewise, there is no ban for cosmetics products containing ingredients tested on animals, even though at least three animal-free methods have been accepted in the EU.

In spite of this, the proposed marketing ban has been a strong incentive for the development of methods to replace animal experiments in toxicological tests. It has undoubtedly contributed to the establishment of internationally accepted criteria for the validation and acceptance of test methods for regulatory purposes. The past efforts have resulted in the EU acceptance of three *in vitro* methods that do not only replace animal tests in the field of cosmetics testing but of all types of chemicals. Now that the first *in vitro* methods have overcome the scientific and bureaucratic hurdles of validation and acceptance, it is hoped that this procedure will be accelerated for future alternative methods.

In the light of these developments, the current endeavours to weaken or even remove the marketing ban from the Cosmetics Directive are not acceptable. As could be shown, the fear that the marketing ban could stand in conflict with WTO rules is not convincing. On the contrary, it goes undisputed that EU citizens do not want animal experiments for new cosmetic products. Moving away from an unconditional marketing ban would therefore be an offence against the "good customs

and public morals” mentioned in Article XXa of the GATT.

In addition, it is surprising that the discussions on the compatibility of the marketing ban with WTO rules do not seem to have progressed in the nine years since the EC legally decided that a marketing ban was to be introduced. It remains unclear what the chances are of defending a marketing ban at the WTO, or to what extent possible conflicts could be settled right from the beginning by means of bilateral or multilateral negotiations. From the point of view of the German Animal Welfare Federation, the implementation of an EU-wide marketing ban is merely a question of political will.

Together with the majority of the European citizens and their representatives in the European Parliament, the European animal welfare organisations want to see an end to the unacceptable suffering of animals for the development and testing of new cosmetic products. The Seventh Amendment to the Cosmetics Directive should therefore include:

- an immediate and unconditional sales ban on new cosmetics products tested on animals and on cosmetic products containing ingredients tested on animals; and
- an immediate ban on animal testing of ingredients and finished cosmetic products within the EU, regardless of the availability of animal-free methods.

The above comments demonstrate that a marketing ban and animal testing ban for new cosmetics are realistic goals. Their implementation in the Seventh Amendment to the Cosmetics Directive would lead to further efforts to develop non-animal testing methods and to speed up their international acceptance, including the making available of additional funding for the development of new non-animal test methods.

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## Update Added in Proof

In January 2003, the European Parliament and the Council of the EU finally agreed on a text for a Seventh Amendment to the EU Cosmetics Directive.<sup>1</sup> The new Directive lays down that a ban on animal testing and on the marketing of cosmetics tested on animals will come into effect six years after the entry into force of the Directive. However,

for three series of tests (repeated-dose toxicity, reproductive toxicity and toxicokinetics) the deadlines for the prohibition of the marketing of cosmetic products for which those tests are used will come into force only after 10 years, with a possibility to further postpone it in the event that no alternative methods are available. The text also states that, as soon as alternative methods are available within the EU, the testing of cosmetic products and ingredients is banned, immediately, as will be their marketing, where alternative methods are available “with due regard to the development of the validation within the OECD”.

From the point of view of animal welfare, it is deeply disappointing that the animal testing and marketing bans are further postponed, and that for three types of tests the deadlines for the bans are even open-ended. However, the obligation to phase out animal experiments for the testing of cosmetic products and ingredients provides a new impetus for speeding up the validation and acceptance of animal-free methods for toxicological endpoints. Under the auspices of the European Commission, a task force, including Commission services and stakeholders such as industry, the OECD and animal welfare, has already been set up to establish time-tables for the phasing out of animal experiments within the deadlines laid down in the Directive.

<sup>1</sup>Anon. (2003). Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products. *Official Journal of the European Union* **L66**, 26–35.

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