Animal Testing and Marketing Bans of the EU Cosmetics Legislation

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I. Introduction

For many years, the EU's legislation on animal testing and marketing bans regarding cosmetic products and their ingredients has been giving rise to controversy. First, the bans were introduced under the regime of the Cosmetics Directive[1], which was subsequently replaced by Regulation (EC) No. 1223/2009 on cosmetic products (hereinafter "EU Cosmetics Regulation")[2]. In this process, the animal testing and marketing bans of Article 4a of the Cosmetics Directive were transferred – with identical content and largely with the same wording – to Article 18 of the EU Cosmetics Regulation, so that the legal issues connected with the bans have basically remained the same. Since the transitional periods for the application of the bans ended on 11 March 2009 and 11 March 2013 (for details, see Article 18(2) of EU Cosmetics Regulation), and the bans as provided by Article 18(1) of the EU Cosmetics Regulation are binding and directly applicable in the EU Member States[3], they must be observed by the affected businesses as of now. Violations are to be sanctioned in the Member States in an effective, proportionate and dissuasive manner (Article 37 of EU Cosmetics Regulation).

Of great importance in this context is the Communication of the European Commission on the animal testing and marketing ban and on the state of play in relation to alternative methods in the field of cosmetics of 11 March 2013[4] which describes, inter alia, the legal framework and the content of the bans. Yet, the Commission Communication could not clarify the legal issues regarding the application of the bans, especially in respect of the wording *"to meet the requirements of this Regulation"*. In order for the ban to take effect, all four paragraphs of Article 18(1) – i.e. the marketing bans in a) and b) and the animal testing bans in c) and d) – demand that animal tests were performed *"to meet the requirements of this Regulation"*.

This element causes particular difficulties in the application of the testing and marketing bans. In the past, this was reflected especially in the lengthy discussion on the relation to the REACH Regulation, if REACH prescribes the performance of animal tests. Currently, in a preliminary ruling procedure (C-592/14) submitted on 19 December 2014 by the High Court of Justice (England and Wales), Queen's Bench Division (Administrative Court) the Court of Justice of the European Union has been asked to review the term *"to meet the requirements of this Regulation"*. This article discusses the legal question raised in this procedure, beginning with the Commission Communication of 11 March 2013.

II. Commission Communication of 11 March 2013

In its Communication of 11 March 2013 (p. 8 seq.) the Commission points out that the majority of ingredients used in cosmetic products are used in many other products (e.g. pharmaceuticals or detergents). As a possible consequence, the relevant legal rules governing these products may demand animal testing. Moreover, regularly the ingredients of cosmetic products also fall under the scope of the REACH Regulation. The REACH Regulation imposes animal tests which must be performed in order to fulfil the registration requirements under REACH. Where animal tests are performed for the ingredients in order

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1 Directive 2003/15/EC which amended Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products. On the bans under the Cosmetics Directive see *Fischer*, Tierversuchs- und Vermarktungsverbote nach der Kosmetikrichtlinie – Auslegungsprobleme und das Verhältnis zu REACH, StoffR 2007, 215 et seq., and *Fischer*, Testing Bans and Marketing Bans under the Cosmetics Directive – How to find a balance between the protection of animal welfare and the right to develop and market cosmetic ingredients, StoffR 2009, 40 et seq. and EFFL 2009, 172 et seq.

2 OJ 2009 L 342/59.

3 See Article 288(2) TFEU which describes the legal character of a EU Regulation.

4 COM (2013) 135 final.

to fulfil the REACH requirements or product-specific legal rules, the question arises whether such data can be used also for the safety assessment of cosmetic products (Article 10 of the EU Cosmetics Regulation).

In this respect, the Commission holds in its Communication of 11 March 2013 that *"animal testing that has clearly been motivated by compliance with non-cosmetics related legislative frameworks should not be considered to have been carried out 'in order to meet the requirements of this Directive/Regulation'. The resulting animal testing data should not trigger the marketing ban and could subsequently be relied on in the cosmetics safety assessment."* Of course – and this is also pointed out by the Commission – the data need to be relevant for the safety assessment of cosmetic products, and the data also need to be of sufficient quality. Furthermore, regarding the enforcement of the bans under Article 18(1) of the EU Cosmetics Regulation, the Commission holds that it is up to the Member States to assess and decide whether the performance of animal tests falls in the scope of the bans (see also Article 22 of the EU Cosmetics Regulation on in-market control).

Thus, the Commission Communication clarifies the interpretation of the wording *"to meet the requirements of this Regulation"* insofar that animal tests which are performed to comply with legal requirements in regulatory frameworks other than the cosmetics legislation do not fall in the scope of the bans of Article 18(1). As a consequence, the subsequent use of data generated from such animal testing for a safety assessment of cosmetic products is not banned by Article 18. In this circumstance, the animal tests are originally not performed for the purpose of fulfilling the requirements of the EU Cosmetics Regulation. Of course, it needs to be established – also regarding REACH – whether or under what conditions the performing of animal tests is necessary at all. With respect to REACH, ECHA (European Chemicals Agency) has expressed its views on various situations (solely cosmetic uses / both cosmetic and non-cosmetic uses).[5]

Yet, the Communication is not entirely clear. Since the Commission refers in its Communication (*"subsequently"*) to a successive second use of the data, the Communication does not address the situation that the generation of data from animal testing has a double purpose right from the start; e.g. to fulfil the mandatory requirements under REACH and the intention to use the data also for a safety assessment under the EU Cosmetics Regulation. Further, pursuant to the wording of the Commission the carrying out of animal tests to comply with other legal rules needs to be *"clearly"* motivated. By inserting the word *"clearly"* the Commission brings forward questions of proof and facts. The statement made by the Commission would also be valid if the word *"clearly"* had not been inserted. This demonstrates that the Commission perceives that, in practice, there may be questions of provability and plausibility, which is then also expressed in the following paragraph of the Commission Communication *("Testing carried out for cosmetics relevant endpoints on ingredients that have been specifically developed for cosmetic purposes and are exclusively used in cosmetic products would in the Commission's view always be assumed to be carried out 'in order to meet the requirements of this Directive/Regulation'.")*. Yet, the wording *"always be assumed"* (in the German version: *"grundsätzlich"*) seems to make it possible that the tests mentioned in the quote, at least as an exception, can be carried out for other purposes than meeting the requirements of EU Cosmetics Regulation.

Furthermore, it should be noted that the Commission Communication departs from the text of Article 18 by referring to *„non-cosmetics related legislative frameworks"*. This phrase does not appear in Article 18(1) where from a) to d) invariably the wording *"requirements of this Regulation"* is used. Semantically, *"this Regulation"* can only be understood as a reference to the EU Cosmetics Regulation, but not any other legal rules which also might be relevant for cosmetic products. By departing from the wording of Article 18, the Commission can also conclude: *"In case animal testing was carried out for compliance with cosmetics requirements in third countries, this data cannot be relied on in the Union for the safety assessment of cosmetics."* Because then – in the logic of the Commission Communication – the animal tests were carried out for purposes of legal provisions related to cosmetic products. The Commission states that it shall be sufficient that one relies on animal data *("The Commission considers that the marketing ban is triggered by the reliance on the animal data for*

5 ECHA, Factsheet, Interface between REACH and Cosmetics regulation, ECHA-14-FS-04-EN.

the safety assessment under the Cosmetics Directive/Regulation, not by the testing as such."). But: In the above-described situation of compliance with cosmetic law requirements of third countries, the animal tests were not carried out to fulfill the rules of the EU Cosmetics Regulation. The frictions shown here between the Commission Communication and the text of Article 18 are the main aspect of the preliminary ruling procedure triggered by the *High Court of Justice.*

III. Reference for a Preliminary Ruling by the High Court of Justice

In a complaint pending before the High Court of Justice, the High Court asked the Court of Justice of the European Union (CJEU) if the marketing ban of Article 18(1) of EU Cosmetics Regulation applies where the safety of cosmetic ingredients is proven by animal test data if third countries (e.g. China, Japan and the USA) require animal test data under national law. The complaint before the High Court of Justice deals with the situation that, according to existing Chinese regulatory requirements, ingredients of cosmetic products must be tested on animals, in order to sell these ingredients in China. Therefore, the question arises whether this affects the marketing of the concerned ingredients in the EU (and the use of data from the animal tests for the safety assessment under Article 10 of EU Cosmetics Regulation), because these ingredients were the object of animal testing.

In the case before the High Court, the plaintiff – the European Federation for Cosmetic Ingredients (EFfCI) – took the view that the text of Article 18(1) b) shows that this question needs to be answered with "no". By contrast, the defendants ((1) Secretary of State for Business, Innovation and Skills (2) Attorney General) argued in favour of an applicability of Article 18(1) b), holding that the marketing ban applies where ingredients of cosmetic products where tested on animals in order to comply with the rules of the EU Cosmetics Regulation and equivalent third country rules. The defendants referred to the purpose of the EU Cosmetics Regulation and the above-quoted passage from the Commission Communication. The interveners ((1) British Union for the Abolition of Vivisection (2) European Coalition to end Animal Experiments) agreed with the defendants and also based their position on the purpose of the EU Cosmetics Regulation, arguing that the Regulation generally aims to ban the sale of cosmetics if their ingredients were tested on animals.

The High Court of Justice found that this issue needs clarification and submitted the following questions to the Court of Justice of the European Union:

"1. Is Article 18(l)(b) of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (1) to be interpreted as prohibiting the placing on the Community market of cosmetic products containing ingredients, or a combination of ingredients, which have been the subject of animal testing where that testing was performed outside the European Union to meet the legislative or regulatory requirements of third countries in order to market cosmetic products containing those ingredients in those countries?

2. Does the answer to question (1) depend on:

(a) whether the safety assessment carried out in accordance with Article 10 of that Regulation to demonstrate that the cosmetic product is safe for human health prior to it being made available on the Community market would involve the use of data resulting from the animal testing performed outside the European Union;

(b) whether the legislative or regulatory requirements of the third countries for which the animal testing was undertaken relate to the safety of cosmetic products;

(c) whether it was reasonably foreseeable, at the time that an ingredient was subjected to animal testing outside the European Union, that any person might seek to place a cosmetic product including that ingredient at some stage on the Community market; and/or

(d) any other factor, and if so, what factor?"

In the following, it will be examined which legal aspects are significant in this respect and how the legal questions arising in this context can be answered.

IV. Legal Assessment

1. Interpretation of EU Law

For an interpretation of secondary legal acts of the European Union (the EU Cosmetics Regulation is

such a secondary legal act of the Union), the Court of Justice of the European Union resorts to various methods of interpretation.[6] According to the CJEU, the text of an EU secondary legal norm is the starting point for interpretation[7].Therefore, the wording of a legal act has decisive weight for its interpretation; it also constitutes the borderline for any interpretation[8]. However, the Court of Justice does not limit itself to the literal interpretation of a legal provision but also refers to further interpretation methods: the teleological interpretation which looks at the rationale of a legal act and the „spirit" of the legislation[9]; the systematic interpretation which observes the system of rules, takes the overall structure of a legislation into account and places singular provisions within the context of a legal act as a whole[10]; and the less weighty historic interpretation which looks at the historic background of the legislation and the legislative process.

Further, it is necessary to interpret a legal act in conformity with higher-ranking EU law. Thus, EU secondary law has to be interpreted in harmony with the European Treaties and fundamental rights of the EU[11]. Therefore, preference should be given to an interpretation which renders the provision consistent with the Treaties and the general principles of EU law. Consequently, legal acts of the EU must not be interpreted in a way which would lead to results that are irreconcilable with the general principles of Union law and, in particular, with the European fundamental laws[12]. Finally – where relevant – an interpretation consistent with WTO law is to be taken into consideration.

2. Wording of Article 18(1) b) of EU Cosmetics Regulation

a. *"To meet the Requirements"*

Article 18(1) b) of EU Cosmetics Regulation contains – as the other three paragraphs of Article 18(1) – the phrase *"to meet the requirements of this Regulation"*. By using the wording *"to meet the requirements... "* the legislator made clear that the purpose for which the concerned animal tests were carried out is decisive. Therefore, the motive why an animal test was performed is a crucial factor with regard to the applicability of Article 18(1). This is also the basic logic of the Commission Communication of 11 March 2013: If a company performs animal tests for a substance only for the purpose of meeting the requirements of other legal rules (i.e. outside the cosmetics legislation), then this set purpose does not trigger the applicability of the marketing bans of the EU cosmetics legislation (and, consequently, the subsequent use of the data for cosmetic uses is permitted in the EU).

The same logic applies with regard to the question whether animal tests which were performed "*to meet the requirements*" of the cosmetics legislation of a third country trigger the marketing bans of the EU Cosmetics Regulation. To this extent, too, only the set purpose of the animal tests and thus the fact for which purpose the animal tests were performed, should be decisive. Then, the next question is (which will be addressed under b)) whether also the third countries' cosmetics legislations are considered relevant circumstances triggering the ban.

Thus, according to the scope of Article 18(1), the purpose why an animal test has been performed is decisive. In the practical application of law, invariably the factual question arises for what purpose the concrete animal test was carried out. To this extent, it is important to differentiate between the analysis of the legal situation on the one side and the questions of facts on the other. In practice, regularly it will be clear for what purpose an animal test is performed. Typically, a company will carry out a costly animal test only if there is a concrete reason to do so. Then, the intention underlying the performance of the animal test is clear, and regularly it will be documented by the company.

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6 See (with sources from the case law of the CJEU) *Borchardt*, in: Lenz/Borchardt, EU-Verträge, 5th ed. 2010, Art. 19 EUV para. 14 et seq., *Schwarze*, in: Schwarze, EU-Kommentar, 3rd ed. 2012, Art. 19 EUV para. 36 et. seq. and *Augsberg*, in: Terhechte, Verwaltungsrecht der Europäischen Union, 2011, § 4 para. 4 et seq.

7 See Case 6/60, *IMM* [1960] ECR 1163, 1192 et seq.; Case 79/77 *Firma Kühlhaus Zentrum* [1978] ECR 611, 619; Case 151/73 *Ireland/Council* [1974] ECR 285, 296; Case 162/73 *Dreher* [1974] ECR 201, 213 et. seq.; Case 73/72 *Bentzinger* [1973] ECR 283, 288.

8 See, for example, case C-313/07, *Kirtruna and Vigano* [2008] ECR I-7907 para. 44.

9 Case 151/73 *Ireland/Council* [1974] ECR I-285 para. 16/17.

10 E.g. Case 22/70 *Commission/Council* [1971] ECR I-263, para. 15/19.

11 Case 374/87 *Orkem/Commission* [1989] ECR 3343 para. 28; Case 41/79 *Testa* [1980] ECR 1981 para. 21.

12 See Cases 46/87 and 227/88 *Hoechst/Commission* [1989] ECR 2859 para. 12.

b. *"Requirements of this Regulation"*

Regarding the wording *"to meet the requirements of this Regulation"* in Article 18(1) b) of the EU Cosmetics Regulation, the wording is also unambiguous insofar, as the reference to *"this Regulation"* can only mean the EU Cosmetics Regulation. "This" Regulation is simply the regulation which contains the provision of Article 18(1) b). By contrast, the approach in the Commission Communication referring to "*non-cosmetics related legislative frameworks"* is irreconcilable with the wording of Article 18(1) b). The same applies for the view of the defendants in the proceedings before the High Court of Justice that "*equivalent third country legislation*" is also included. In a literal interpretation of Article 18(1) b), tests which are performed for fulfilling cosmetics legislation of third countries are not carried out for fulfilling the requirements of the EU Cosmetics Regulation.

What is meant by *"requirements"* is clearly shown by the High Court of Justice which refers to "*regulatory requirements*". Thus, Article 18 refers to the regulatory requirements prescribed by the EU Cosmetics Regulation and, in particular, concerning the safety assessment under Article 10 of this Regulation. By contrast, it would not be convincing if one wanted to assume that the wording in Article 4a of the Cosmetics Directive *"in order to meet the requirements of this Directive"* was to be understood in the light of the primary goal of the Cosmetics Directive, i.e. the protection of human health; leading to the consequence, that it follows from the wording that also cosmetic products or ingredients tested in animal tests outside the Community would fall under the marketing ban, because these were also carried out to meet public health requirements. Such concept was embodied in the Opinion of the Advocate General *Geelhoed* of 17 March 2005 in case C-244/03[13]. This interpretation is not supported by Article 4a (1) of Cosmetic Directive or Article 18(1) of EU Cosmetics Regulation: If one aims to fulfil third country requirements, the animal testing is not directed at fulfilling the requirements of the EU Cosmetics Regulation (or of the Cosmetics Directive).

13 Para 81, 86 of the Opinion.

c. Performing Animal Tests Inside or Outside the European Union?

The High Court of Justice phrases the first question for preliminary ruling in a way that animal tests which were carried out to comply with the legal provisions of a third country were also performed outside the European Union *("that testing was performed outside the European Union to meet the legislative or regulatory requirements of third countries in order to market cosmetic products containing those ingredients in those countries")*. Whether an animal test was geographically performed inside or outside the European Union is actually not decisive for the application of the marketing bans (Article 18(1) a) and b) of the EU Cosmetics Regulation). Because – unlike wording in Article 18(1) c) and d) – the words *"within the Community"* were not included in a) and b). Consequently, in a) and b) only the set purpose of the animal tests and not the place where they were performed is decisive.

Therefore, the question posed by the High Court of Justice regarding the applicability of the marketing ban of Art 18(1) b) equally arises if animal tests for compliance with the legal rules of third countries were performed inside the European Union, in order to be able to market the cosmetic products containing such ingredients in these third countries. By contrast, if animal tests of a cosmetic ingredient were performed geographically in a third country with the goal of providing evidence that the requirements of the EU Cosmetics Regulation are fulfilled and in order to enable marketing in the EU, then the ban of Art 18(1) b) EU Cosmetics Regulation is applicable.

3. Teleological, Historical and Systematic Interpretation

It follows from the above that an interpretation based on the wording of Art 18(1) b) EU Cosmetics Regulation leads to the result that the marketing ban, as provided the text of the legal norm, does not apply if the ingredients of a cosmetic product were tested in animal tests, if these tests were carried out to comply with the legal rules of third countries, in order to enable the marketing of cosmetic products containing such ingredients in these third countries. Now, it needs to be examined whether this interpretation (which leads to the conclusion that the first

question from the High Court of Justice should be answered in the negative) stands when the abovementioned other interpretation methods are applied.

a. Teleological Interpretation

As described above, within the teleological interpretation of a legal norm, the Court looks at the rationale of a legal act and seeks the „spirit" of the legislation. The marketing ban according to Article 18(1) b) of the EU Cosmetics Regulation serves the purpose of replacing animal tests by alternative testing methods for reasons of animal welfare. In the light of this purpose one might argue that the marketing ban of Article 18(1) b) could categorically apply when animal tests are performed in connection with ingredients of cosmetic products; i.e. also in case of performing animal tests to fulfil third country requirements. This could be substantiated with an even stronger reduction of animal testing and with further enhancing animal welfare. However, it should be noted that also a teleological interpretation has its limitations in the clear wording of a legal provision, especially if infringements lead to sanctions. It was already pointed that the wording of Article 18(1) b), when referring to *"requirements of this Regulation"*, is clear. If animal tests performed to comply with the rules of third country cosmetic legislation trigger the marketing ban, then the limits of the wording of the provision would be exceeded.

Moreover, it is doubtful whether such extended interpretation of Article 18(1) of the EU Cosmetics Regulation would contribute to reducing animal tests. If a company performs animal tests for the safety assessment of cosmetic ingredients, because it wants to market cosmetic products in a country which mandatorily requires the performing of animal tests, then animal testing is indispensable for market access. Such animal tests cannot be prevented by barring the data obtained in such animal tests for a marketing in the EU. But if animal tests are performed, anyway, in order to meet third country requirements, then the goal of reducing animal tests cannot be achieved by extending the marketing ban to such third country tests. Therefore, the purpose of the animal testing bans does not necessarily require to apply the marketing ban of Art 18(1) b) to cases where an animal test is performed to fulfil the legal provisions of a third country.

The applicability of the marketing ban of Art 18(1) b) in such situation would, as a consequence, deny manufacturers of cosmetic product ingredients from third countries market access to the EU, or such market access would at least be substantially impaired. At the same time, pressure would be exerted on third countries to change their national laws in such a manner that animal testing is given up in the cosmetics sector. Both approaches collide with World Trade Law. This will be discussed later.

b. Historical Interpretation

As described above, the animal testing and marketing bans were already established in the EU Cosmetic Directive (Article 4a) and then transferred with identical content into the EU Cosmetics Regulation (Article 18). In its proposal for introducing the bans in the Cosmetics Directive, the Commission stated the following: *"Conversely, the European Union will need to accept data from studies conducted in animals, that may be used as supporting data for cosmetic ingredients/products. Such studies would have been conducted to satisfy the legislative demands of third countries in any case. Mutual recognition is the key to this approach – it would be inappropriate for the European Union to demand the repetition of a test using an alternative methods, as this would set up a barrier to trade and may impact upon any favourable position taken upon the acceptability of European in vitro data."*[14]

This shows that the European legislator already considered, at that time, the situation where animal tests are performed in third countries outside the EU to fulfill the legal requirements of those countries. The Commission rightly points to two aspects: (i) the animal tests would have been performed anyway, because the tests were necessary to comply with third country legislation; (ii) a refusal to recognise the animal tests would impair trade and would be inappropriate.

Therefore, the historical background of the European legislation supports the acceptance of animal tests by the EU if such testing was performed to fulfil third country requirements. This is not questioned by the recitals of the EU Cosmetics Regulation, which do not address this issue. Recital 45 only refers to

14 COM (2000) 189 final, under 2.3.

mutual recognition to the extent that the EU – in relation to third countries – should strive for recognition of alternative test methods developed in the European Union, in order to avoid a repetition of the assessment via animal testing in third countries. But the international law principle of reciprocity is only complied with, if, in turn, the EU is willing to accept tests prescribed in third countries and to recognize animal test data.

c. Systematic Interpretation and Internal Consistency

The overall structure of the EU Cosmetics Regulation does not give any clues on how to interpret the element *"to meet the requirements of this Regulation"* within Article 18(1) b) of the EU Cosmetics Regulation. Of importance, though, is a consistent interpretation of Article 18(1) b). If the Commission holds in its Communication of 11 March 2013 that the marketing bans do not apply if animal tests are intended to fulfill regulatory requirements outside the cosmetics sector, then this basic logic also needs to be applied to the case that animal tests are performed to comply with the cosmetics-related legal rules of third countries. Only this way, but not with the above-described interpretation by the Advocate General *Geelhoed*, can an inherently consistent application of Article 18(1) b) be achieved.

d. Interpretation in the Light of Primary EU Law

Further, an interpretation of secondary Union law has to take primary Union law into account, especially in respect of the fundamental rights guaranteed under EU law. In 2009, I analysed in the *Zeitschrift für Stoffrecht*[15] the conflict between the animal testing and marketing bans under the EU cosmetics legislation and the EU guarantees of fundamental rights. In this context, the fundamental right to freely pursue an economic activity and to conduct business (Article 16 of the Charter of Fundamental Rights of the European Union)[16] and the principle of proportionality, as recognised by the Court of Justice of the European Union, are of particular importance.[17]

European fundamental rights are an integral part of the general principles of Union law. Initially developed by the Court of Justice of the European Union, the fundamental rights are meanwhile recognized by Article 6(1) of the Treaty of the European Union as legally binding as they are set out in the Charter of Fundamental Rights of the European Union.[18] Therefore, the interpretation of the EU Cosmetics Regulation needs to concur with Article 16 of the Charter of Fundamental Rights and with the principle of proportionality. Regarding the restriction of economic activities, this has been outlined by the Court in such a manner that the lawfulness of the prohibition of an economic activity is subject to the condition that the prohibitory measures are appropriate and necessary in order to achieve the objectives legitimately pursued by the legislation in question; when there is a choice between several appropriate measures recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued.[19] Due to the intensive effects that result from the animal testing and marketing bans, the impacted legal positions must be carefully weighted: on the one side, the legitimate goal of animal welfare (enshrined in Art 13 TFEU), on the other side, the law to free economic activity (and also the objective of health and consumer protection which require proof of the safety of cosmetic products and their ingredients).[20]

For the problem assessed here and for the wording *"to meet the requirements of this Regulation"*, fundamental rights are important to the extent that it stands in contradiction to the principle of proportionality if the marketing ban becomes effective, even though the goal of minimising animal testing cannot be achieved. This situation arises if (due to the existing legal requirements) animal tests need to be performed anyway; be it to fulfill the requirements of EU law outside the cosmetics sector, or be it to fulfill the requirements of third country cosmetics-related

15 *Fischer*, StoffR, 2009, 40 et seq.

16 Regarding the fact that those endowed with fundamental rights can also be legal entities and that not only companies headquartered inside the EU but also companies headquartered in third countries can be endowed with fundamental rights under Article 16 of the Charter: *Jarass,* Charta der Grundrechte der Europäischen Union, 2nd ed. 2013, Art. 16 para. 11 and Art. 51 para. 56 et seq.

17 *Fischer*, StoffR, 2009, 40, 43 seq.

18 Regarding the fundamental rights protection in the EU see e.g. *Arndt/Fischer/Fetzer*, Europarecht, 11th ed. 2014, para. 395 et seq.

19 See Case 331/88 *Fedesa* [1990] ECR I-4023, paragraph 13, which reflects the established case law of the CJEU.

20 *Fischer*, StoffR 2009, 40, 45 seq.

laws. In both cases, animal tests are performed to meet the relevant legal requirements. But if the animal test data are available anyway, it does not seem necessary to prohibit their use for the safety assessment under the EU cosmetics legislation. Therefore, also the fundamental rights of EU law support a "No" to the first question submitted by the High Court of Justice and deem Article 18(1) b) EU Cosmetics Regulation as non-applicable if the animal tests were performed to fulfill the legal requirements of third countries outside the European Union, in order to be able to market cosmetic products containing such ingredients in those third countries.

e. Interpretation in the Light of WTO Law

This finding is supported when, as a last step, the impacts of WTO law are taken into account. Even though the WTO rules, due to its nature and structure, have no direct effect within European Union law[21], the Court of Justice did recognise that secondary Union law needs to be interpreted according to the wording and purpose of WTO law.[22] Relevant is here Article III:4 GATT (General Agreement on Tariffs and Trade) as well as Article 2.1 TBT (Agreement on Technical Barriers to Trade) which guarantee the mandatory equal treatment of foreign and domestic products, i.e. imported products must be treated no less favourable than domestic like-products. But if cosmetic products are treated differently only because of the method of their production (more precisely: the testing of safety), there is a conflict with the non-discrimination principle, because the methods of quality assurance do not affect the likeness of the product[23], and a justification on the grounds of Article XX GATT seems difficult.[24]

Already when enacting Art 4a Cosmetics Directive, the reconcilability of the bans with Art III:4 GATT was discussed controversially during the legislative procedure[25]. Because of this, the European Commission proposed within the legislative procedure to give up the introduction of marketing bans and to limit this legislation to an EU-wide animal testing ban. Giving less consideration to world trade concerns[26] the marketing bans where introduced after all. But the conflict with World Trade Law can be reduced, if the marketing of cosmetic import goods from third countries is not banned in the EU when the safety of the goods were proven by animal tests which were performed according to the legal requirements of the third country. Therefore, also an interpretation taking World Trade Law into account supports the non-applicability of the marketing ban of Article 18(1) b) of the EU Cosmetics Regulation.

V. Conclusions

It results from the above considerations that the marketing ban of Article 18(1) b) of the EU Cosmetics Regulation should not apply to cosmetic products whose safety assessment relies on results of animal testing, if such tests were conducted outside the European Union to meet the legal requirements of third countries. In particular, the clarity of the wording of Article 18(1) b) of the EU Cosmetics Regulation supports this and cannot be eroded by teleological considerations. Moreover, extending the marketing ban to such cases would constitute a conflict with the EU fundamental rights and also with World Trade Law.

If the facts of the case are the following: a manufacturer of cosmetic ingredients wants to place his products on the market in a third country (outside the EU) and generates animal test data, because that country prescribes animal testing for this purpose and, at a later stage, the manufacturer wants to expand on the EU market and exports his goods there – then, the marketing ban of Art 18(1) b) EU Cosmetics Regulation should not be applicable; because

21 See, inter alia, Cases C-300/98 and C-392/98 Dior [2000] I-11344, para 43 et seq.

22 See, Case C-245/02 Anheuser Busch [2004] I-11018, para 42.

23 See *Winter*, in: *Gesellschaft für Umweltrecht, Umweltrecht im Wandel*, 2001, p. 88 that it is a fundamental approach within in World Trade Law that different ppm (production and processing methods) do not affect the likeness of products, because they have no influence on the product quality.

24 Therefore, Herrmann, *Zeitschrift für Lebensmittelrecht* 2003, 399, 411 seq. pleads for an infringement of WTO law.

25 See the explanation of the European Commission for the an amendment of the Cosmetics Directive in OJ EC 2000, C311 E/134 which reads under item 1.2.3: *"Article III.4 of the General Agreement on Tariffs and Trade (GATT) says that imported products shall be treated no less favourably than like products of national origin. As the test method does not have any physical effect on the product, discrimination on this basis could be considered to be contradictory to WTO rules, in particular Article III.4 of the GATT. In this context it is doubtful whether Article XX of the GATT 1994 could provide sufficient justification for measures of this nature."*

26 Still in the amended proposal for a directive on cosmetic products (OJ EC 2002 C51 E/385) the Commission rejected a marketing ban: *"It is not in conformity with WTO-rules and likely to be challenged."* The Commission held that a unilateral Community marketing ban would be contrary to the policy of a multilateral approach to animal welfare trade issues.

then, the animal tests were not performed to fulfill the requirements of the EU Cosmetics Regulation but to meet the requirements of third country cosmetics legislation. This must equally apply if the manufacturer of a cosmetic ingredient strives, right from the beginning, for global marketing of his products and thus, at the same time, for market access in the EU and in third countries. Where a third country (like China) prescribes the performance out of animal tests and, consequently, the manufacturer carries out the required animal tests, he does this only for this very reason. Then, the carrying out of animal tests is not performed to comply with the rules of the EU Cosmetics Regulation.

Question 2(c) of the High Court of Justice needs to be answered in this light, too. To this extent, the High Court asked whether, at the moment in time when an ingredient was tested in animal testing outside the European Union, it was "*reasonably foreseeable*" that it might be tried at a later stage to place a cosmetic product, which contains this ingredient, on the Community market. According to the above explanations, the circumstance if the placing on the Community market is "*reasonable foreseeable*" is not a relevant factor. Moreover, such criterion would be too vague, anyway. Also, where marketing in the EU is desired right from the start, this is not changed by the fact that animal tests have been performed to meet the cosmetics law requirements of a third country. As a consequence, relying on animal test data, which were generated to meet third country legal requirements, should be permissible (question 2a) of the High Court of Justice). Further, it plays no role whether the third country legal requirements – to comply with which animal tests were performed – concern the safety of cosmetic products or not (question 2b) of the High Court of Justice). In both cases, the marketing ban of Article 18(1) b) of the EU Cosmetics Regulation is not applicable.

It remains to be seen how the Court of Justice of the European Union will answer the questions submitted by the High Court of Justice. Earlier complaints against the bans were rejected as inadmissible by the Court of First Instance of the European Communities and also by the European Court of Justice[27]. But now, in the preliminary ruling procedure initiated by the High Court of Justice, the Court of Justice will have to take position for the first time on the content of the animal testing and marketing bans of EU Cosmetics Law.

27 Case T-196/03 *European Federation for Cosmetic Ingredients (EFfCI) v European Parliament and Council of the European Union* [2004] II-4268, and the appeal decision in Case; C-113/05 P; case C-244/03 *French Republic v European Parliament and Council of the European Union* [2005] I-4059.