# LAW, BEAUTY AND WRINKLES. FIRM POINTS AND OPEN ISSUES AFTER THE EU COSMETICS REGULATION

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The full entry into force in July 2013 of Regulation 2009/1223 on cosmetic products (henceforth Cosmetics Regulation, CR) brings with it a host of problems only partly solved by the said Regulation which opens – or leaves open – a series of issues deserving the attention of legal scholars.

This paper intends to examine the following topics: 1. The Regulation as basis of a comprehensive regulation of the cosmetics sector; 2. Standardization of products and selection of market players; 3. Distribution and competition; 4. Animal testing between bio-ethics and trade barriers; 5. New models of products liability; 6. Consumers and cosmetics: pre-sale and post-sale protection.

#### TABLE OF CONTENTS

- I. THE REGULATION AS BASIS OF A COMPREHENSIVE REGULATION OF THE COSMETICS SECTOR
- II. STANDARDIZATION OF PRODUCTS AND SELECTION OF MARKET PLAYERS III. DISTRIBUTION AND COMPETITION
- IV. Animal testing between Bio-Ethics and Trade Barriers
- V. NEW MODELS OF PRODUCTS LIABILITY
- VI. CONSUMERS AND COSMETICS: PRE-SALE AND POST-SALE PROTECTION VII. CONCLUSIVE REMARKS

## I. THE REGULATION AS BASIS OF A COMPREHENSIVE REGULATION OF THE COSMETICS SECTOR

A few data are necessary: in 2011 the cosmetic industry in Europe was worth over 70 billion Euros. It employed directly around 150.000 persons, to whom one should add the many hundreds of thousands engaged in the distribution and sales process. Germany and France have the largest national industries, each producing goods worth approximately 15 billion Euros (although France exports 4.4 billion compared to Germany's 2.4 billion). Italy and the UK also have a large share, ranging between 10.5 and 11 billion Euros. Among the top five operators in the world, two are European (L'Oreal, no. 1 and Unilever, no.3); two are from the US (Procter & Gamble, no.2 and

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Estée Lauder, no.4) and one is Japanese (Shisheido). The presence of extremely big companies, however, does not seem to influence the number of SMEs: 700 in both France and Italy, 300 in Germany. Per capita spending in the EU is around € 90 (but in Germany, France, Italy, the UK and Spain it is over € 150)¹.

We are therefore facing a strong and dynamic sector which has a vast basis in household goods (soaps, toothpastes, bath foams, generally qualifying as toiletries) but presents itself mostly as a luxury good, where image, branding, packaging and marketing are perceived as essential. The cosmetic industry sells something that is entirely non-material and subjective: beauty and, especially in the case of perfumes, seduction.

The CR is not a novelty. Actually it is the consolidated version of a very long history of regulation which started way back in the mid-seventies with Directive 76/768, and has grown incrementally to the point –clearly marked by policy decisions – of being turned into a Regulation, and therefore a harmonized system of binding rules for all member States<sup>2</sup>.

This transformation has been relatively smooth, without the usual complex and sometimes noisy confrontation between the Commission and industry with trade unions and consumers playing their part and other vocal stakeholders taking sides, that characterizes the development of regulation in other sectors. Regulation in the cosmetics sector has been mostly industry-driven and although obvious concessions have had to be made, compliance can be expected to be high, inasmuch as the rules reflect what is generally common practice among operators. This policy assessment clearly is not without consequences on the interpretation of the picture which emerges from Regulation 1223 and its connections with the rest of the legal system.

The data is drawn from the following sources: Statista. The Statistics Portal available at <a href="http://www.statista.com/statistics/271773/per-capita-expenditure-on-cosmetic-products/">http://www.statista.com/statistics/271773/per-capita-expenditure-on-cosmetic-products/</a>; Cosmetic Industry Statistics in Europe, available at <a href="http://www.reportlinker.com/d014793271/Cosmetic-Industry-Statistics-in-Europe.html">http://www.reportlinker.com/d014793271/Cosmetic-Industry-Statistics-in-Europe.html</a>; Global Insight, A Study of the European Cosmetics Industry (prepared of the European Commission), available at <a href="http://edz.bib.uni-mannheim.de/daten/edz-h/gdb/07/study-eu-cosmetics-industry.pdf">http://edz.bib.uni-mannheim.de/daten/edz-h/gdb/07/study-eu-cosmetics-industry.pdf</a>; For data on the Italian market see the data provided by Ermeneia (ed.), Beauty Report 2013. Quarto Rapporto sul valore dell'industria cosmetica in Italia, Franco Angeli 2013.

<sup>&</sup>lt;sup>2</sup> Preamble 4: "This Regulation comprehensively harmonises the rules in the Community in order to achieve an internal market for cosmetic products while ensuring a high level of protection of human health." See the paper presented at the Rome Conference "Il diritto dei cosmetici: Regolazione, responsabilità, bio-etica" (Jan.28, 2014) by G. Benacchio, *Il diritto europeo dei cosmetici: dall'armonizzazione all'uniformazione delle regole* 

A further preliminary remark is necessary. When analysing the CR one is struck by the lack of academic writings on the topic. What can be found are general descriptions of its content and some articles related to its impact in this or that member state<sup>3</sup>. The most commonly considered topic is selective distribution, a competition issue that was born in the cosmetics sector. One could assume that cosmetics do not deserve scholarly attention. Notwithstanding the importance of the descriptive approach, this article will endeavour to highlight a number of issues that appear to deserve more attention, especially for their impact on the rest of the regulatory system.

In fact the CR draws a fairly complete outline of the rules which govern the sector<sup>4</sup>: 71 preambles, 40 articles and 10 annexes may not necessarily be considered very ample (in the food sector regulations can be much longer). What is important is that it is quite a comprehensive text and although there are obvious cross-references to other pieces of EU legislation, a civil law *aficionado* might easily rename the CR the Cosmetics Code<sup>5</sup>.

One should compare the CR to similar regulatory frameworks. The first thing one notes is that the definition is relatively loose:

«"Cosmetic product" means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to

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<sup>&</sup>lt;sup>3</sup> In the classical Poucher's Perfumes, Cosmetics and Soaps (10th edn, H. Butler ed.) (Kluwer 2000) there is a chapter of about 40 pages (pp. 625-645) by P.D. Wilkes, Legislation and safety regulations for cosmetics in the United States, the European Union and Japan. Its content is mostly descriptive, and is directed to a public of industry professionals. In France, which one would imagine to be more sensitive to the issue, the only handbook on the topic, Ch. Roquilly, Le droit des produits cosmétiques, Economica, dates back to 1991. More recently, a brief outlook by V. Depadt-Sebag, Le droit et la beauté (Ière et IIème parties), Petites Affiches 2000, nn. 95 and 96. In Italy, previously the only general articles to be found on the topic were by M.V. De Giorgi, Produzione dei cosmetici e tutela della salute, in Giurisprudenza commerciale 1978, 839; and by G. Ponzanelli, Appunti civilistici in merito alla l. 11 ottobre 1986, n. 713, sulla produzione e la vendita dei cosmetici, in Le nuove leggi civili commentate 1987, 79. Only very recently see M.C. Paglietti, Cosmetics law e tutela del consumatore. La disciplina dei cosmetici tra persona e mercato, soluzioni contrattuali e aquiliane, in 3 Quaderni di Diritto, Mercato, Tecnologia (2012), [available on-line athttp://www.dimt.it/wp-content/uploads/2013/12/MariCecilia-Paglietti-Anno-III-%E2%80%93-Numero-1-%E2%80%93-Novembre-2012Marzo-2013trascinato.pdf where there are ample citations of both EU case law and literature from various legal systems.

<sup>&</sup>lt;sup>4</sup>See the paper presented at the Rome Conference "Il diritto dei cosmetici: Regolazione, responsabilità, bio-etica" (Jan.28, 2014) by S. Amorosino, La disciplina dei cosmetici: un caso di studio per il diritto dell'economia.

<sup>&</sup>lt;sup>5</sup> One should note, however, that the CR does not set out penalties, but simply states (as most EU legislation), that they "should be effective, proportionate and dissuasive" (Preamble 66).

cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours». [italics added]<sup>6</sup>

This functional definition obviously leaves a certain degree of uncertainty as to where the boundary lies between cosmetics and other products, typically pharmaceutical products or hybrid products which may have similar functions but are of internal use<sup>7</sup>.

However it is worth pointing out that it is up to the producer what sector he wishes to operate in and therefore whether his product falls within the CR. Once this choice has been made the rest of the regulations ensue. There may be areas of uncertainty, but they appear to be marginal, especially if one considers that the companies in the cosmetics sector often operate, though parent companies, in neighbouring sectors, and presumably make their decisions well before putting the product on the factory line.

The system therefore is built around prior industrial decisions – does one want to produce a cosmetic or some other product ? – following which the whole CR applies (or does not apply).

Presumably the blurred border is between cosmetics and on the one side, health foods and beverages (which are of internal use and therefore do not fall within the definition) and on the other side, over-the-counter pharmaceuticals whose main functions are curative and are usually advertised. Again one should compare this objective regulation, which depends on the nature of the product and determines the whole structure of the enterprise and its productive system, with other forms of sectorial regulation such as financial markets, electronic communications and transport, where the starting point is subjective: a firm requires an authorization or a licence; from that qualification stems the nature of the services it can render, and how it should render them.

One generally considers the financial markets, etc. as regulated markets but if one want to avoid indulging in nominalism, one can quite properly state that the market for cosmetics also falls within the notion. This should be considered especially when tackling

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<sup>&</sup>lt;sup>6</sup> Preamble 7 contains an even longer list

<sup>&</sup>lt;sup>7</sup> Preamble 6: "This Regulation relates only to cosmetic products and not to medicinal products, medical devices or biocidal products. The delimitation follows in particular from the detailed definition of cosmetic products, which refers both to their areas of application and to the purposes of their use."

<sup>&</sup>lt;sup>8</sup> See, for an attempt to distinguish the two in French law Roquilly, cited at fn 2, p. 154 ff. (concluding that the law is uncertain).

competition issues: the market, and the field where firms compete has, by and large, been drawn by regulatory decisions.

### II. STANDARDIZATION OF PRODUCTS AND SELECTION OF MARKET PLAYERS

The last comment suggests a reading of the CR for its competitive (pro, or anti) effects. Theoretically the production of cosmetics is an open market, where any new business may enter. Market concentration is not so high as to favour exclusionary practices. There are certainly some large enterprises that compete among themselves and through subsidiaries and parent companies they also compete in other fields but at the same time there are hundreds of SMEs. Undoubtedly, the CR introduces a regulatory barrier to entry into the market: conformity to CR prescriptions has a standardizing effect which restricts innovation – one of the key elements, and goals, of competition. This standardization clearly has strong policy reasons (consumer health and safety concerns; animal bio-ethics). But this means that competition moves from the product to its marketing and advertising practices, where moneys will have to be spent, and which represent – when extremely high in proportion to the cost – a typical entry barrier. This does not mean to advocate lowering standards of quality and safety and circumventing the provision of article 169 TFUE, which requires a "high level of consumer protection"<sup>10</sup>, in order to ensure a more competitive market; rather to point out that –at least in the EU - there is always a mix of interests between competition and regulation, which from a legal-realistic point of view are used quite indifferently and in varying quantities, with the intent of reaching public goals.

This is a further element to be considered when applying competition principles to this market.

One should also consider the important regulatory role of the Scientific Committee for Consumer Safety (SCCS), especially in the fast-developing field of nanomaterials<sup>11</sup> which requires a great amount of research and will in the near future make the

<sup>&</sup>lt;sup>9</sup> The complex French regulation before the CR (but compliant with the previous EC legislation) is presented by Roquilly, cited at fn. 2, p. 16 ff.

<sup>&</sup>lt;sup>10</sup> According to Preamble 9 "a risk-benefit reasoning should not justify a risk to human health".

<sup>&</sup>lt;sup>11</sup> Although there are some doubts about what exactly is meant by "nano-materials": "it is necessary to develop a uniform definition for nano-materials at international level" (Preamble 29). And article 2, para. 3, is even more explicit: "In view of the various definitions of nano-materials published by different bodies and the constant technical and scientific developments in the field of nanotechnologies, the Commission shall adjust and adapt point (k) of paragraph 1 to

difference between the European industries and those of other regions (typically the US). The CR expressly states that the use of nano-materials (as well as of other materials) should be governed by the principle of precaution<sup>12</sup>. The notion is widely challenged for its fuzzy theoretical grounds and in its practical applications<sup>13</sup>. It appears to be an inescapable levy in favour of vocal anti-scientific movements. At any rate, the provisions substantially equate those industries most subject to the precaution principle: pharmaceuticals, cosmetics and food. However, one can detect the reason behind this apparently stringent regulation – vividly represented by the 1328 forbidden substances listed in Annex II, and the 256 partially forbidden substances listed in Annex III<sup>14</sup> – which primarily standardizes production in the EU; it creates a protective barrier against external competition that does not comply with the same standards. And this is strengthened by the protection of intellectual property rights, both trademarks and patents<sup>15</sup>. The issue deserves to be analysed – but not in this limited article – from the perspective of global trade and the possibility for European cosmetic companies to conquer new market shares without giving up their share at home and being challenged under WTO rules<sup>16</sup>.

#### III. DISTRIBUTION AND COMPETITION

From a commercial point of view one of the reasons for the success of the cosmetic industry in Europe has been the special distribution rules which it has been able

technical and scientific progress and to definitions subsequently agreed at international level." For an example of these differences see J. Moore, New Zealand's Regulation of Cosmetic Products Containing Nano-materials, 9 Bioethical Enquiry 185 (2012).

<sup>&</sup>lt;sup>12</sup> See article 16 CR

<sup>&</sup>lt;sup>13</sup> The obvious reference is to C.R. Sunstein, *Laws of Fear: Beyond the Precautionary Principle*, Cambridge U.P., 2005 (especially Ch. 3).

<sup>&</sup>lt;sup>14</sup> See, already before the CR A. Reinhart, *Process of Harmonisation of the Laws relating to Cosmetic Products Goes On – Positive List of Hair Dye Substances*, in Eur. Food & Feed L. Rev. 362 (2006)

<sup>15</sup> Preamble 15: "The European cosmetics sector is one of the industrial activities affected by counterfeiting, which may increase risks to human health. ... In-market controls represent a powerful means of identifying products that do not comply with the requirements of this Regulation." On the protection of trademarks in the cosmetics sector see G. Guglielmetti, Cosmetici e marchio ingannevole, in Rivista diritto industriale 1988, I, 424; and Roquilly, cit. at fn. 2, p. 55 ff. On the patentability of perfumes see the classical work by J.P. Pamoukdjian, Le droit du parfum, LGDJ 1982; and of cosmetics Roquilly, cit. at fn. 2, p. 41 ff. The ECJ in the l'Oréal, Lancôme, Garnier v. eBay case (C-324/09) decided in 2011 has protected the cosmetic producers against the on-line auction site on the basis of trademark law.

<sup>&</sup>lt;sup>16</sup> It is interesting to note that the ASEAN Cosmetic Directive at its Article 4 states that "Member States shall adopt the Cosmetic Ingredient Listings of the EU Cosmetic Directive 76/768/EEC including the latest amendments". It is not yet clear if this provision will now refer to the 2009 CR. The ASEAN Directive is part of the *Globalization of Cosmetic Regulations* (J. Winter Blaschke, in 60 Food Drug L. Rev. 413 (2005).

to obtain as an exception to general competition principles clearly set out in (now) articles 101 and 102 TFEU.

The main reason behind the "selective distribution" (a legal euphemism for refusal to sell) in the *Givenchy*<sup>17</sup> and *Yves Saint-Laurent*<sup>18</sup> cases decided by the ECJ was that the cosmetic industry was engaged in selling "luxury goods" requiring specialized channels of distribution that would not dilute the aura surrounding those products. Surprisingly (or maybe not) the CR does not mention, even in its lengthy preambles, the word "competition", and more specifically does not intervene directly in the distribution process<sup>19</sup>.

However this silence – which appears to apply the Latin maxim *quieta non movere* (*i.e.* leave things, and case law, how they are) – suggests a more complex scenario. In the CR the distributor of the product is given the unprecedented role of controller and guarantor. In particular the distributor must ensure that all safety regulations have been complied with, and must act appropriately even if it has (only) "reason to believe" that conformity is lacking.

Considering the structure of the market and the fact that distributors are in the front line in deciding strategies to penetrate or strengthen a position in the market, one can imagine that this increased responsibility is a trade-off for maintaining competition exceptions in line with the selective distribution procedure.

The CR expressly establishes that the distributor "covers" both wholesalers and retailers<sup>20</sup>. It is therefore understandable that it must be able(through contract) to choose and control them<sup>21</sup>This would be extremely difficult to do if it were compelled to sell to any wholesaler, especially bearing in mind the role that e-commerce plays in the field of cosmetics and the difficulty of guaranteeing compliance by much bigger business entities, often established in non-EU countries<sup>22</sup>.

<sup>19</sup>See the paper presented at the Rome Conference "Il diritto dei cosmetici: Regolazione, responsabilità, bio-etica" (Jan.28, 2014) by C. Camardi, *La distribuzione "vigilata" dei cosmetici nel mercato unico. Aspetti contrattuali.* 

<sup>&</sup>lt;sup>17</sup> See Case No IV/33.542 *Parfum Givenchy*; subsequently see the *Kruidvat BVBA* case (C-70/97 P), in which the Commission was sided by Givenchy.

<sup>&</sup>lt;sup>18</sup> Case T-19/92 Leclerc v Commission

<sup>&</sup>lt;sup>20</sup> Preamble 14

<sup>&</sup>lt;sup>21</sup> see Roquilly, cited at fn. 2, p. 113 ff. (distribution in perfume stores) and p. 153 ff. (distribution in pharmacies).

<sup>&</sup>lt;sup>22</sup> The producers do not appear to be altogether satisfied by the ECJ Pierre Fabre decision (case C-439/09). See Ch. Vilmart, Les nouveaux risques pour la distribution sélective des produits cosmétiques, 2011 Semaine Juridique, E/A, n. 3, 1028; Eadem, Distribution sélective des produits cosmétiques Pierre Fabre et Internet. La CJUE fait une réponse tautologique, in 2011 Semaine Juridique, E/A, n. 47, 1833; M.

From a marketing point of view, producers have made of their websites a powerful tool to increase not only sales but also brand recognition<sup>23</sup>. One could object that this prevents consumers from buying – on-line – from the same vendor different products by different producers, somehow promoting tying contracts. But the reply could be that consumers can freely choose among a variety of producers who sell on-line, and if they do not want to bear extra delivery costs they can easily and freely choose at their nearest retailer. Once again one is confronted with the possible incompatibility of "pure" competition rules in a highly regulated market.

## IV. ANIMAL TESTING BETWEEN BIO-ETHICS AND TRADE BARRIERS An important part of the CR<sup>24</sup> is devoted to (the prohibition of) animal testing and indicates a preference for alternative methods of testing.

The normative *portmanteau* is the Protocol on protection and welfare of animals annexed to the Amsterdam Treaty in 1997, in which animals are qualified as "sentient beings"<sup>25</sup>. If one reads the few lines of the Protocol one easily detects considerable compromise in the wording: member States are to "pay full regard to the welfare requirements of animals, while respecting the legislative or administrative provisions and customs of Member States relating in particular to religious rites, cultural traditions and regional heritage". The same words have been inserted into article 13 of the 2007 Lisbon Treaty.

The CR's position against animal testing is a significant departure from the 2010/63 Directive on the protection of animals used for scientific purposes, which instead allows, albeit with significant limits and procedures, animal testing, especially in the pharmaceutical sector.

The result is surely a success for the animal-care pressure groups. There are however some unanswered questions.

In the first place, one could ask whether human testing might become the alternative to animal testing. In the second place, alternative methods of testing might incur considerably increased costs in the production process, which would then be

<sup>24</sup>Article 18

Malaurie-Vignal, L'interdiction de la revente en ligne de produits dermo-cosmétiques ne peut être contractuellement stipulée, 2013 Contrats, Concurrence, Consommation, n. 4, comm.76

<sup>&</sup>lt;sup>23</sup> see the doubts expressed by Roquilly, cited at fn. 2, p. 247 ff. on the possibility of extending the rules for luxury cosmetics to toiletry

<sup>&</sup>lt;sup>25</sup>See the paper presented at the Rome Conference "Il diritto dei cosmetici: Regolazione, responsabilità, bio-etica" (Jan.28, 2014) by F. Rescigno, Esseri animali: res o soggetti. L'animal testing quale possibile ostacolo verso la soggettività animale.

passed on to consumers. Thirdly, if cosmetics must abide by the precaution principle this would suggest extensive testing in order to ensure their complete safety. Finally one should consider that the prohibition might encourage marketing solutions that in some cases would bring the product under a pharmaceutical label: a cosmetic developed through animal testing is qualified as a drug, stressing its curative, rather than aesthetic, function.

This does not in any way imply that animal testing should be re-introduced for cosmetic products, but it does point out some issues that do not appear to receive sufficient attention in the preambles of the CR and its *travaux préparatoires*.

However the ban on animal testing has considerable market implications. On the one side it has a protectionist effect, inasmuch as foreign products – and we have seen that three of the topfive cosmetic and toiletry producers are non-European – would not be allowed to enter the EU if they had been tested on animals. But on the other side the CR already anticipates that animal testing might become a dangerous tool in international commerce, especially if other countries (the obvious reference would be to the FDA procedures in the USA) were to deny marketability precisely because European cosmetic products had not been sufficiently tested<sup>26</sup>.

#### V. NEW MODELS OF PRODUCTS LIABILITY

The CR does not apparently contain specific provisions concerning liability for cosmetics that may have damaged health or property. It would therefore seem that the legal regime in these cases should be that set by the earliest, and best-studied, EU consumer legislation, Directive 85/374 on liability for defective products. The systematic interpretation being suggested in this article is that the CR widely supersedes the defective products directive and establishes, as *lex specialis*, a different, and more stringent, regime of liability<sup>27</sup>.

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<sup>&</sup>lt;sup>26</sup> See Preamble 45: "The Commission should also endeavour, within the framework of European Community cooperation agreements, to obtain recognition of the results of safety tests carried out in the Community using alternative methods so as to ensure that the export of cosmetic products for which such methods have been used is not hindered and to prevent or avoid third countries requiring the repetition of such tests using animals."

<sup>&</sup>lt;sup>27</sup> See the papers presented at the Rome Conference "Il diritto dei cosmetici: Regolazione, responsabilità, bio-etica" (Jan.28, 2014) by S. Whittaker, *Product liability, 'putting the product into circulation' and corporate structure*; and by F. Cafaggi, "Supply chains" e distribuzione della responsabilità nel regolamento 1223/2009.

In the first place there is a significant increase in the number of persons or entities that may be held liable. The CR imposes the designation of a "responsible person" burdened with a number of obligations, the violation of which one can reasonably expect (at least in continental legal systems) to be a source of liability<sup>28</sup>.

One must include, always from a subjective point of view, the role played by the distributor, who must ensure, together with the obligations already imposed on the responsible persons, conformity of labelling, expiry data and relevant information, and safe storage and transport conditions<sup>29</sup>. Both responsible persons and distributor must also provide, if requested, all necessary information concerning the supply chain<sup>30</sup>. They are also compelled to notify any serious undesirable effects and take appropriate measures to prevent them from repeating themselves.

From an objective point of view, considering that the general principle of precaution and the listing of thousands of prohibited, or partially prohibited, substances in the various Annexes to the CR are meant to protect the health of consumers, one can reasonably suppose that non-compliance with that principle and the use or misuse of listed substances is, *prima facie*, in continental legal systems, ground for liability, putting the burden of the proof on the producer, the responsible person, the distributor.

One can therefore expect that, in case of damage to consumers, the CR will be invoked as *lex specialis* in respect of the *lex generalis* represented by the defective products directive. This poses a further question, *de iure condendo*. Is Directive 85/374 still adequate nearly 30 years after its enactment? When it was passed it was clearly a ground-breaking piece of legislation but now, after dozens of directives and regulations in the field of consumer protection and scores of decisions by the ECJ, it appears at best a rusty tool, no longer in line with the goal set by article 169 of the TFEU ("a high level of consumer protection"). The contrast appears to be not only in comparing directive 85/374 with subsequent legislation and case-law in the field of extra-contractual obligations, but also in relation to the quasi-strict liability regime one finds in most consumer contract directives and regulations.

<sup>&</sup>lt;sup>28</sup> See article 5 of the CR

<sup>&</sup>lt;sup>29</sup> See article 6 of the CR

<sup>&</sup>lt;sup>30</sup> Article 7 sets a 3 year period of traceability. The rule is set not only for safety reasons, but also for economic reasons: "Ensuring traceability of a cosmetic product throughout the whole supply chain helps to make market surveillance simpler and more efficient" (Preamble 12)

Clearly the CR is a sectorial regulation, but if one starts adding the various "exceptions" (financial markets, pharmaceutical products, transport, electronic communications) one can detect a trend which ends up by swallowing the rule.

## VI. CONSUMERS AND COSMETICS: PRE-SALE AND POST-SALE PROTECTION.

Another aspect not present in the CR that is equally important is the relevance of the general regulation of consumer contracts.

While it is rare for serious accidents to occur that impair the health of the user and for which the extra-contractual liability will apply<sup>31</sup>, the most common case will be consumers who, dissatisfied with a product, invoke a misleading advertisement or information concerning that product and therefore, its non-conformity.

This aspect is relevant especially if one considers that many cosmetics are advertised promising certain results (white teeth, slimmer body, elimination or reduction of wrinkles, etc.)<sup>32</sup>.

This specific feature of cosmetics marketing should be read in the context of Directive 1999/44 (the consumer sales directive). In particular article 2, para. 2, letter d) states that conformity should be established "taking into account any public statements on the specific characteristics of the goods made about them by the seller, the producer or his representative, particularly in advertising or on labelling".

Therefore, quite independently of eventual (and unlikely) express guarantees (disciplined by article 6 of the Directive) the line followed is that which was opened by

<sup>&</sup>lt;sup>31</sup> In the Morhange case, concerning a talcum powder which caused 36 deaths and hundreds of seriously injured among infants, the product had been accidentally contaminated by high quantities of hexachlorophene, a potent biocide: see the decisions by the TGI Pontoise 11 February 1980 and by the Courd'Appel Versailles 5 December 1980, in Dalloz 1981, Chr. 87 ff. 32 For some doubts on the relevance of the different objects of advertisement see Roquilly, cited at fn. 2, p. 212 ff. In the Estée Lander v. Lancaster case (C-220/98) the ECJ held that the cosmetics legislation in force at the time did " not preclude the application of national legislation which prohibits the importation and marketing of a cosmetic product whose name incorporates the term 'lifting' in cases where the average consumer, reasonably well informed and reasonably observant and circumspect, is misled by that name, believing it to imply that the product possesses characteristics which it does not have". And the decision also stated that "It is for the national court to decide, having regard to the presumed expectations of the average consumer, whether the name is misleading" eventually "commissioning, in accordance with its national law, a survey of public opinion or an expert opinion for the purposes of clarification". Previously, instead, always the ECI in the Clinique Laboratoires case (C-315/92) held that the "Clinique" trademark was not deceitful and therefore could not be prohibited.

the package tours Directive (1999/314), in which advertising statements in favour of the consumer prevail over the written contract.

Considering that the sale of cosmetics is a typical over-the-counter transaction, and imagining that the leaflets which accompany the product will be fraught with warnings, the problem will be the interpretation of the possible contrast between advertising statements and information contained in the leaflet.

However one should take into account that advertising (and packaging) come before the purchase and are meant to promote it<sup>33</sup>. Only after the sale can the consumer actually read the leaflet. It would therefore appear reasonable for the producer to be bound by his public statement, while the instructions and warnings contained in the leaflet should be relied upon in the case of misuse of the products, but surely not to render illusory the results promised in the advertisements. Other relevant information, e.g. on maximum durability after the product has been opened, is also generally contained on the leaflet or on the label<sup>34</sup>.

From this point of view one can see the other aspect of public statements in as much as they violate the preeminent public interest to fair dealings. As a matter of fact it appears more likely that the protection of consumers will be borne by the unfair commercial practices Directive (2005/29) and the misleading advertising Directive (1984/450) and by the heavy fines which have been introduced<sup>35</sup>. One notices here a typical issue of consumer contracts when their economic value is relatively low. It is extremely difficult for the consumer to prove significant damages arising from the ineffective cosmetic product, and therefore it is reasonable to expect that his/her only claim will be for the cost of the product. But if the reimbursement is not spontaneous, it is unlikely that the consumer will engage in expensive and time consuming litigation. And

<sup>&</sup>lt;sup>33</sup> According to Preamble 10 it is necessary to avoid "confusion with foodstuffs".

<sup>&</sup>lt;sup>34</sup> The labeling provision (article 19 CR) is the typical EU all-comprising provision: where all that information will fit is a permanent challenge to the packaging/marketing division. The strict interpretation of the labeling provisions is endorsed by the ECJ in case C-169/99 (Hans Schwarzkopf case): "It is not impossible for practical reasons (...) to set out the compulsory warnings in full on the container and packaging of a cosmetic product in the language or languages prescribed in the Member State in which it is to be marketed, where the producer or distributor wishes to label the product in nine languages, including eight official languages of the Community, for economic considerations and in order to facilitate the movement of the product within the Community, and this entails abbreviating those warnings on the container and packaging".[italics added]

<sup>&</sup>lt;sup>35</sup>Article 20, para. 1, CR: "In the labelling, making available on the market and advertising of cosmetic products, text, names, trademarks, pictures and figurative or other signs shall not be used to imply that these products have characteristics or functions which they do not have." However, "It should be possible to claim on a cosmetic product that no animal testing was carried out in relation to its development." (Preamble 52)

even the eventual ADR procedures do not appear to be particularly appealing from a cost/benefit analysis<sup>36</sup>.

#### VII. CONCLUSIVE REMARKS

For lawyers the most interesting aspect of the CR is seeing how an existing, developed and highly sophisticated market can be defined and governed through regulation.

On the longitudinal axis the CR sets the boundaries of the market by providing a definition of what is meant by "cosmetic product". This allows us, to a certain extent, to distinguish the cosmetics market from that of other products, typically pharmaceuticals and food & beverages.

This area is relevant for regulatory purposes, although it is reasonable to consider that it may (and will) be subdivided for competition purposes on the basis of the traditional criteria of substitutability and interchangeability. However the fact that cosmetics fall under a specific regulation makes it unlikely that any will be included in a relevant market with non-cosmetic products.

On the vertical axis we can observe that the regulated market includes a variety of enterprises, from producers to importers, to distributors, to wholesalers, to retailers and, obviously, consumers. Some advocates of animal rights might even include animals, in as much as they are entitled to be excluded from experimentation and testing.

This vertical perspective – typical of all EU sectorial regulations – establishes a legal relationship between the various actors in the market, setting out their respective duties and creating a framework within which private law governance may operate, mostly through very detailed and complex contracts<sup>37</sup>. From this point of view the CR enhances the increasing hybridization of public law constraints and private law autonomy.

It also defines the legal status of each actor, giving certainty to where they stand vis-à-vis public authorities. Although the CR does not introduce independent regulatory agencies, the role of the SCCS and of its decisions will inevitably increase, so the role of

<sup>&</sup>lt;sup>36</sup>See the paper presented at the Rome Conference "Il diritto dei cosmetici: Regolazione, responsabilità, bio-etica" (Jan.28, 2014) by M. C. Paglietti, *Le controversie e la loro risoluzione*.

<sup>&</sup>lt;sup>37</sup> See again the paper by F. Cafaggi, cited at fn.

the Commission will become central because it must receive all the relevant information concerning the product before it is placed on the market<sup>38</sup>

What should be considered – mostly for imported cosmetic products – is the phenomenon of "member State shopping" in order to take advantage of the principles of free movement of goods and of mutual recognition<sup>39</sup>.

Finally, the formalization of the cosmetics market and of its actors allows a more precise and effective application of the extensive EU consumer legislation. Inasmuch as the European cosmetics industry appears to be quite united in its aims<sup>40</sup>one can expect that increased exposure to consumer expectations will encourage the formation of best practices in order to avoid or solve controversies with consumers.

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These notes are meant to provide a general overview of a topic which is acquiring, through the CR, increasing legal importance; their intention is to promote a wider and more profound analysis able to clarify the many aspects that have not – for reasons of conciseness – been examined here.

<sup>&</sup>lt;sup>38</sup> See article 15 CR on the notification procedure

<sup>&</sup>lt;sup>39</sup> The principle is expressly re-stated in article 9 CR

<sup>&</sup>lt;sup>40</sup> On the role that industry associations have been playing over these decades see Roquilly, cited at fn. 2, p. 32 ff.