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International Journal of Hygiene and Environmental Health

journal homepage: www.elsevier.de/ijheh



Contact allergens for armpits—Allergenic fragrances specified on deodorants

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ARTICLE INFO

Article history:

Received 14 October 2011

Received in revised form

21 December 2011

Accepted 26 December 2011

Keywords:

Antiperspirants
Axillary dermatitis
Consumer protection
Contact allergy
Cosmetics directive
Cosmetic products
Cosmetic Regulation
Deodorants
Fragrances
Labeling
Risk management

ABSTRACT

According to the so-called “26 allergens rule” 26 supposedly allergenic fragrances must be specified on the containers of cosmetic products if they are present above 0.001% in leave-on products and, 0.01% in rinse-off products. This declaration is meant to inform the consumers of potential risks of skin sensitizers in the products. As many consumers of deodorants suffer from allergic or irritant contact dermatitis in the axillae, the presence of allergens in deodorants deserves special attention.

The objective of this study was to find answers to the following questions: Does compulsory labeling lead to omission of strong allergenic fragrances in deodorants? Is there a difference in the use patterns of strong and weak allergens? What is the quantitative exposure to fragrances by deodorants? Is the situation in Germany different from other European countries? Is there a difference between deodorants for men and for women?

I tested the implementation of the “26 allergens rule” and compiled which allergenic fragrances are specified on the containers of deodorants. Three market studies were conducted in Germany in 2008, 2010 and 2011. The labels of a total number of 374 deodorants were analyzed as to whether any of the “26 allergens” were listed. The frequency of each allergen in the deodorants was compared with results from previous studies by other authors.

It was found that up to 83% of the deodorants contain at least one of the “26 allergens” and that up to 30% of all products contain strong allergens above the threshold for labeling (0.001% in the product). The most frequently listed allergens are medium or weak allergens. In comparison with other authors, the frequency of the “26 allergens” in products is slightly smaller in these recent studies for the German market. There is no significant difference between deodorants for men and women, as far as the labeling of the “26 allergens” is concerned.

The results show that the mandatory labeling procedure as designed in the “26 allergen rule” is not suitable to guarantee consumer safety for deodorants. As long as consumers are not informed about allergens in products in an easy to understand and transparent way, a compulsory pictogram on the container should inform them about possible risks.

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Introduction

Deodorants are used to mask and reduce body odor caused by the bacterial breakdown of perspiration. They contain usually perfume and antimicrobials that decrease the number of bacteria and hence the unpleasant smell of the microbial secretion compounds. As some fragrances show biocidal activity they fulfil both purposes simultaneously. Deodorants can contain compounds, called antiperspirants, which reduce the amount of sweat produced, usually by aluminium salts which obstruct the glands in the axillae. “Antiperspirants” can also be defined as the products which reduce the sweat production on the skin, whereas “deodorants” exert only the odoriferous and antimicrobial action (Darlenski and Fluhr,

2011). As many products on the European market are a combination of both, deodorants and antiperspirants are treated as one big product group here and no differentiation is made between them in the following study.

Deodorants are widely used, as sprays, creams, sticks or roll-ons. The German market of deodorants came to 705 million Euros in 2010 and was the cosmetic product group with the biggest increase compared to the two previous years (www.IKW.org, market data). 65.2% of adult men and 73.3% of adult women apply deodorants at least once per day (Lorenz et al., 2011).

Most consumers do not suffer from any unwanted side effects of deodorants. However, negative effects of fragrances like asthma or migraine headaches, neurotoxicity, carcinogenicity, or induction of psychological or other detrimental effects are observed and discussed in literature (e.g. Cadby et al., 2002a; Thyssen et al., 2009; Umweltbundesamt, 2006). Musk metabolites, coumarin or benzophenone show endocrine disrupting activity (European

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Commission, 2002). Ingredients in some deodorants have the potency to induce contact allergy (Johansen et al., 1998; Uter et al., 2007; Zirwas and Moennich, 2008). In the study by Heisterberg et al. (2011) deodorants were the major culprits for fragrance contact allergy, closely followed by scented lotions. In the study by Nardelli et al. (2011), deodorants were the third most important cosmetic group to provoke allergic contact dermatitis. The skin of the armpits is especially sensitive as the moisture and warmth enhances the penetration of substances through the skin. Itching and irritation can be induced by irritants present in deodorants or are first signs of a contact allergy (Johansen et al., 2011). Allergic reactions in axillae can be provoked by lower concentrations of fragrance allergens than on other parts of the skin (Johansen et al., 1998).

Fragrance industry has been aware of potential effects of fragrances on human health for a long time. Since the 1960s, they have been evaluating the toxicological effects of fragrance ingredients, however the safety evaluation is still to a large degree self regulated by the fragrance industry (Cadby et al., 2002b; Klaschka and Kolossa-Gehring, 2007; Schumann, 2001). “Parfum” in the ingredient list of the container stands for up to several hundred fragrance ingredients. The main legal instrument in the EU to deal with fragrance sensitizers is the “26 allergen rule” for cosmetics and washing and cleansing products. The presence of 26 presumptive allergenic fragrances must be indicated in the list of ingredients of the containers when the concentration of one of the 26 exceeds 0.001% in leave-on products such as deodorants. This was originally laid down in Article 1 (10) of Directive 2003/15/EC (EC, 2003) and is transferred to the new Cosmetic Regulation (EC, 2009) in Art. 19(1)g and Annex III (List of Substances which Cosmetic Products must not contain except subject to the restrictions laid down) where the 26 fragrances are now integrated. For some of these compounds, there are additional restrictions, e.g. maximum authorized concentrations in the finished product in the Cosmetic Directive which will be taken over in the new Cosmetic Regulation by 2013. The pros and cons of the “26 allergens rule” were analyzed in detail in Klaschka (2010).

The 26 fragrance compounds listed in “the 26 allergens rule” have different allergenic potencies. 21,000 patients were examined by use of an extended patch test by the Information Network of Departments of Dermatology (Schnuch et al., 2007b). This study found out that some of these fragrances are important allergens (Group I: tree moss extract, oak moss extract, Lyril (hydroxymethylpentyl-cyclohexene carboxaldehyde), hydroxycitronellal, isoeugenol, cinnamic aldehyde, farnesol), some are clearly allergenic, but less important in terms of sensitization frequency (Group II: cinnamic alcohol, citral, citronellol, geraniol, eugenol, coumarin, Lilial (2-(4-tert-butylbenzyl)propionaldehyde), amyl cinnamic alcohol, benzyl cinnamate) and some are (extremely) rare sensitizers or even non-sensitizers (Group III: benzyl alcohol, linalool, methylheptin carbonate, alpha-amyl-cinnamic aldehyde, alpha-hexyl-cinnamic aldehyde, D-limonene, benzyl salicylate, benzyl benzoate, anisyl alcohol, gamma-methylionon (3-methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one)). The substance names on the containers of cosmetic products are INCI names (see Inventory of ingredients employed in cosmetic products. Section II: Perfume and aromatic materials, SCCNFP, 2000), whereas dermatologists use different names for some compounds. As the present publication deals with contact allergy the nomenclature of dermatologists is used. For synonyms, CAS numbers and further information about these compounds see Klaschka (2010). The present study used the classification by Schnuch et al. (2007b) of the allergenic potential of the “26 allergens” as it was based on a very comprehensive data basis, knowing that there are also other classifications (Klaschka, 2010).

Other ingredients in deodorants which might be critical for human health or the environment, such as aluminum salts,

ethanol, preservatives (such as Triclosan), or nanoparticles are not addressed here further.

Methods

I selected three random samples of deodorants available in German retail shops. In 2008, I selected 66, in 2010, 200 and in 2011, 108 deodorants. It was not possible to follow the same products for several years and record changes, as names, compositions, designs and labels of cosmetic products change very frequently. The European Consumer Centre Austria estimated that 25% of cosmetic products are replaced or changed per year (Europäisches Verbraucherzentrum Wien, 2009). The data for 2008 given here are part of the data collection described in Klaschka (2010) where a total of 742 cosmetics and washing products were analyzed in the same way. The sample 2008 consisted of products from four big companies on the German market, whereas the samples analyzed in 2010 and 2011 came from around 20 producers, most of them also world-wide known manufacturers. The ingredient lists for the sample raised in 2008 was checked on the producers’ homepages and spot checks in 2008/2009 showed that the declarations on the internet coincided with those on the containers of the products on the shelves of the retailers. I recorded which of the “26 allergens” were specified in the lists of ingredients and grouped these allergens in three classes depending on their allergenic potentials according to Schnuch et al. (2007b). I also recorded whether “parfum” is listed in the list of ingredients. Conclusions are drawn under the proviso that I do not know whether the samples are representative for the German market.

I then made a synopsis of my data with data published by other authors who used similar or different approaches.

Results

The percentage of deodorants without perfume or one of the “26 allergens” went down from 8% in 2008 to 1% in 2011 (Table 1). The percentage of deodorants that contain one of the “26 allergens” went up from 53% in 2008 to 83% in 2011. The maximum number of allergenic fragrances listed per product was 14. More than half of the products contain at least a strong or a medium allergen (50% in 2008, 75%, in 2010, 69% in 2011). The presence of these substances must only be indicated on the label, if the concentration is above 0.001% in the products. In addition, chemical analyses demonstrated that the “26 allergens” are not always listed correctly on the label (Kantonslabor Basel, www.kantonslabor-bs.ch). For these two reasons, it must be assumed that there are more deodorants which contain these compounds.

Fig. 1 shows that most deodorants (95%) recommended for sensitive skin contain perfume and 15% contain at least one strong allergen above the threshold for labeling.

Table 2 shows that there is no major difference between the deodorants for men and women, as far as the presence of perfume and of the “26 allergens” are concerned. Neutral deodorants (deodorants which are not specifically recommended for men or for women on their labels) contain less of the “26 allergens”: 41% of neutral deodorants contained at least one of the “26 allergens” compared to 87% of deodorants for men and 93% of deodorants for women. 11% of neutral deodorants contained at least one strong allergen compared to 27% of deodorants for men and 23% of deodorants for women.

Table 3 shows a comparison with previous studies by other authors. The selection criteria for the deodorants under scrutiny were different in each study compiled here as well as the methods of analysis. This heterogeneous origin of data must be remembered when the data are compared with each other. Rastogi et al.

Table 1

Declarations of fragrances in the ingredient lists of random samples of deodorants on the German market. The fragrances specified were grouped according to their allergenic potentials described by Schnuch et al. (2007b). The product data were obtained by the ingredient lists on the producers' homepages in 2008 or by the ingredient lists on the containers of the products in 2010 and 2011.

	2008	2010	2011	Sum
Number of deodorants analyzed	66 (100%)	200 (100%)	108 (100%)	374 (100%)
Number of deodorants without perfume or single fragrances	5 (8%)	8 (4%)	1 (1%)	14 (4%)
Number of products where at least one of the 26 allergens is listed	34 (52%)	160 (80%)	90 (83%)	284 (76%)
Maximum number of substances of "the 26 allergens rule" listed on one product	10	14	13	14
Number of products where at least one of the 26 allergens which are strong allergens (I) according to Schnuch et al., 2007 is listed (Names of the strong allergens on the product labels)	5 (8%) Lyrall (=hydroxy-methylpentyl-cyclohexene carboxaldehyde)	60 (30%) oak moss extract, farnesol, Lyrall (=hydroxy-methylpentyl-cyclohexene carboxaldehyde), isoeugenol, hydroxycitronellal, tree moss extract	14 (13%) Lyrall (=hydroxy-methylpentyl-cyclohexene carboxaldehyde), isoeugenol, hydroxycitronellal, farnesol	79 (21%)
Maximum number of strong allergens listed on one single product	1	3	2	3
Number of products where no strong allergen (I), but at least one of the medium allergens (II) according to Schnuch et al. (2007) is listed. (Names of the medium allergens on the product labels)	27 (41%) Lilial (=2-(4-tert butylphenyl) propionaldehyde), citronellol, citral, geraniol	91 (45%) benzyl cinnamate, Lilial (=2-(4-tert butylphenyl) propionaldehyde), cinnamyl alcohol, citronellol, citral, coumarin, eugenol, geraniol	61 (56%) Lilial (=2-(4-tert butylphenyl) propionaldehyde), citronellol, citral, coumarin, eugenol, geraniol	180 (48%)
Maximum number of strong and medium allergens listed on one single product	5	9	7	9

Table 2

Most deodorants are designed for men or for women and some are neutral. I checked on the labels of the deodorant samples raised in 2010 and 2011 whether they contained perfume or the "26 allergens".

Deodorants	For women	For men	Neutral
Number	50 + 84 = 134 (100%)	41 + 79 = 120 (100%)	17 + 37 = 54 (100%)
Containing perfume	47 + 79 = 126 (95%)	41 + 78 = 119 (99%)	17 + 31 = 48 (89%)
Containing at least one of the "26 allergens"	43 + 73 = 116 (87%)	37 + 75 = 112 (93%)	10 + 12 = 22 (41%)
Containing at least one strong allergen	8 + 28 = 36 (27%)	4 + 24 = 28 (23%)	1 + 5 = 6 (11%)

(1998) quantified 21 fragrance ingredients of 73 deodorants purchased in Denmark, England, France, Germany, and Sweden by gas chromatography and mass spectrometry (Table 3A). Some of them are identical with the "26 allergens". The concentrations detected in the deodorants ranged between 1 and 26,960 ppm. The direct comparison with the indications on the containers (Table 3B–F) is not possible, as the threshold limit for labeling in deodorants

is 0.001% (=10 ppm) and Rastogi et al. (1998) did not indicate how many samples were below this limit, as this was not relevant at that time, when the "26 allergen rule" was not yet in force. This might be the main reason, why the percentage of deodorants containing the respective fragrance is the biggest in Table 3A compared to the other studies (Table 3B–F). Buckley conducted a market study in the UK in 2006 and checked which fragrances from the 26 allergen rule were listed on the containers (Table 3B). She concluded that there is "ongoing consumer exposure to the most frequent sensitizers in FM I" (Fragrance Mix I) (Buckley, 2007). The Danish market study published by Rastogi et al. (2007a) analyzed in the ingredient lists of 97 deodorants whether the "26 allergens" are listed (Table 3C). They found that in almost 70% of the deodorants investigated one or more of the "26 allergens" were present according to the ingredient lists on the products. I checked on the ingredient lists of 66, 200 and 108 deodorants collected in 2008, 2010 and 2011 whether the "26 allergens" are listed (Table 3D–F).

Most fragrances followed a similar pattern: the percentage of deodorants was higher in 1996–2006, went down in 2008 and went slightly up again in 2010 and 2011. The percentages found in 2008 were lowest for nearly all fragrances compared to previous or later studies. Especially the percentages of strong allergens were low in the deodorant sample analyzed in 2008. Benzyl alcohol was the only fragrance ingredient that was found more often in 2010 and 2011 compared to 2006. This fragrance is also used as a preservative.

The most frequently found strong allergens are present in fewer products (up to 53%) than the most frequently applied medium (up to 88%) and weak allergens (up to 97%).

Two strong allergens (tree moss extract and oak moss extract), two medium allergens (benzyl cinnamate and amyl cinnamic alcohol) and two weak allergens (anisyl alcohol and methylheptin carbonate) were listed on less than 5% in all samples.

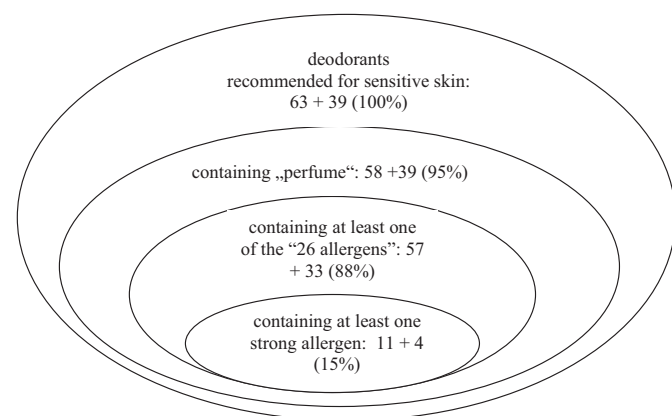


Fig. 1. Some manufacturers describe their deodorants on the product label as "sensitive", "mild", "sanft" (soft), "besonders mild" (exceptionally soft) "hautberuhigend" (skin soothing), "schützt und pflegt irritierte Haut" (protects and nurses irritated skin), "sanft duftender Schutz" (soft scented protection) on the container. In the sample analyzed in 2010 (first number) 63 products had one of these words on the label and in 2011 (second number) 39 (out of a total of 200 respectively 108 products). On 95% of these products "perfume" was listed. On 88% of these products at least one of the 26 allergens and on 15% at least one strong allergen was specified. The maximum number of strong and medium allergens listed on a single product recommended for sensitive skin was 6.

Table 3

Number of deodorants which contain the “26 allergens” in comparison with previous studies by other authors.

Number of deodorants analyzed Products from	(A) 73 Denmark, England, France, Germany, Sweden	(B) 17 UK	(C) 97 Denmark	(D) 66 Germany	(E) 200 Germany	(F) 108 Germany
Year	1996	2006	2006	2008	2010	2011
Method	Chemical analysis	Label control	Label control	Homepage of producers and label control	Label control	Label control
Strong allergens						
Lyrall (=hydroxy-methylpentyl- cyclohexene carboxaldehyde)	37 (53%)	5 (29%)	29 (30%)	5 (8%)	32 (16%)	10 (9%)
Hydroxycitronellal	35 (50%)	4 (24%)	24 (25%)	0	20 (10%)	3 (3%)
Farnesol	n.d.	0	13 (13%)	0	11 (6%)	1 (1%)
Isoeugenol	20 (29%)	3 (18%)	8 (8%)	0	4 (2%)	1 (1%)
Cinnamic aldehyde	12 (17%)	0	1 (1%)	0	1 (0.5%)	0
Tree moss extract	n.d.	0	2 (2%)	0	1 (0.5%)	0
Oak moss extract	n.d.	0	4 (4%)	0	2 (1%)	0
Medium allergens						
Citronellol	57 (81%)	15 (88%)	58 (60%)	17 (26%)	97 (49%)	39 (36%)
Geraniol	53 (76%)	12 (71%)	43 (44%)	17 (26%)	96 (48%)	49 (45%)
Lilial (=2-(4-tert-butylbenzyl)propion- aldehyde	36 (51%)	8 (47%)	43 (44%)	15 (23%)	74 (37%)	37 (34%)
Coumarin	40 (57%)	8 (47%)	29 (30%)	0	70 (35%)	36 (33%)
Eugenol	40 (57%)	6 (35%)	24 (27%)	0	37 (19%)	8 (7%)
Citral	n.d.	2 (12%)	23 (24%)	13 (20%)	38 (19%)	18 (17%)
Cinnamic alcohol	27 (39%)	2 (12%)	11 (11%)	0	4 (2%)	2 (2%)
Benzyl cinnamate	n.d.	0	3 (3%)	0	5 (3%)	2 (2%)
Amyl cinnamic alcohol	n.d.	0	–	0	0	0
Weak or non-allergens						
D-Limonene	n.d.	11 (65%)	47 (48%)	24 (36%)	116 (58%)	57 (53%)
Linalool	68 (97%)	12 (71%)	47 (48%)	22 (33%)	109 (55%)	59 (55%)
Gamma-methylionon (=3-methyl-4-(2,6,6-tri-methyl-2- cyclohexen-1-yl)-3-buten-2-one	43 (61%)	10 (59%)	41 (42%)	16 (24%)	68 (34%)	31 (29%)
Alpha-hexyl cinnamic aldehyde	50 (71%)	10 (59%)	29 (30%)	11 (17%)	56 (28%)	26 (24%)
Benzyl alcohol	n.d.	3 (1%)	15 (15%)	0	55 (28%)	31 (29%)
Benzyl salicylate	34 (49%)	12 (71%)	35 (36%)	8 (12%)	52 (26%)	18 (17%)
Benzyl benzoate	50 (71%)	8 (47%)	22 (23%)	0	25 (13%)	9 (8%)
Alpha-amyl-cinnamic aldehyde	22 (31%)	2 (12%)	9 (9%)	0	4 (2%)	5 (5%)
Anisyl alcohol	n.d.	0	2 (2%)	0	1 (0.5%)	0
Methylheptin carbonate	n.d.	0	1 (1%)	0	0	0

(A) Rastogi et al. (1998) analyzed the concentration of fragrances in deodorants by GC/MS (n.d. no data).

(B) Buckley (2007) analyzed the ingredient lists of 300 personal care and household products whether the “26 allergens” are listed, 17 of the products were deodorants.

(C) Rastogi et al. (2007a) analyzed the ingredient lists of 97 deodorants whether the “26 allergens” are listed.

(D–F) I analyzed the ingredient lists of deodorants whether the “26 allergens” are listed in 2008, 2010 and 2011.

The percentages refer to all deodorants in a sample, not only to the deodorants which contain fragrances or perfume.

Cosmetic ingredients present above 1% in the final product are listed on the products in descending order of weight. To get an idea about the amounts of each of the “26 allergens” in the products I calculated the mean values of the positions in the ingredient lists of all products in the sample analyzed in 2010. I could not find a significant difference in the positions in the ingredient lists between strong, medium and weak allergens. This might be due to the fact that the position of the fragrances does not follow the fractions in the products, because they are present below 1%. Ingredients present below 1% are listed in any order at the end of the ingredient list (Cosmetics Regulation Art. 9 (1 g)) (EC, 2009). This result does not allow to tell whether the concentrations of strong and weak allergens in the products differ. Quantitative chemical analysis of the products would be needed to answer this question.

Discussion

Perhaps safer, but not safe

On one hand, most deodorants still contain the “26 allergens” (Table 1), on the other hand, the frequency went down compared to previous studies by other authors for other European countries (Table 3). It cannot be excluded that today these substances are substituted by other compounds of similar or higher hazard, e.g.

isoeugenol derivatives (Rastogi and Johansen, 2008; Tanaka et al., 2004) or Majantol (Schnuch et al., 2007a). It must also be assumed, that in my samples several deodorants contain some of the “26 allergens” at concentrations below the threshold concentrations for labeling. Rastogi et al. (2007a) detected these fragrances in 35% (8 out of 23) of their sample of deodorants at concentrations below the threshold for labeling.

It is not possible to say whether the situation in Germany is different from other European countries as the situation might have changed there, too.

Significantly more men have an allergic contact dermatitis to fragrances due to deodorants than women in Denmark (Heisterberg et al., 2011). Under the assumption that the Danish deodorants are similar to those in Germany, this difference cannot be explained by the ingredient lists. No major differences were found in my samples between the deodorants for men and those for women (Table 2). Furthermore, on average women apply deodorants more often than men (Lorenz et al., 2011). It is only a hypothesis that more women than men use neutral deodorants which contain less fragrances and less of the “26 allergens”, but if this is true this might be one of the reasons for the lower allergic contact dermatitis in women compared to men. Further research on this observed difference between men and women might help to identify further causes for the development of contact allergy.

In my study, up to 30% of the deodorants contain at least one strong allergen (Table 1). Lyrall is the most frequently listed strong allergen in my deodorant samples and was found in 8–16% of the deodorants. Rastogi et al. (2007a) detected Lyrall at higher concentrations than recommended by the SCCP in one third of the analyzed deodorants. This is not against the law, but it does not protect consumers. Contact allergy to Lyrall is much higher in Europe compared to North America where Lyrall is present at lower concentrations in deodorants (Nardelli et al., 2008). In 2004, the SCCNFP demanded a maximum concentration in the finished product of 0.02% (SCCNFP, 2004). In 2009, also the International Fragrance Association (IFRA) recommended that the maximum concentration of Lyrall should be reduced to 0.02% for category 2 products (deodorants) (www.ifraorg.org). In my study, fewer deodorants contained Lyrall above the threshold for labeling than in previous studies. This might be a reaction to these SCCNFP and IFRA proposals, that manufacturers used lower concentrations than 0.001% or no Lyrall.

The 10 most frequently named fragrances in all deodorants analyzed are not strong allergens, but belong to Groups II and III. The allergenic potential of geraniol, which was the second most frequent medium allergen in my study, might be underestimated (Nardelli et al., 2011). It is true, that the two most frequently listed fragrances, limonene and linalool, belong to Group III of rare and non-sensitizers, but they oxidize easily in contact with air and the oxidized products are potent sensitizers (Karlberg et al., 1994; Matura et al., 2005; Skold et al., 2008).

My analysis showed that oak moss extract is present in only two deodorants in 2011. The SCCP recommended not to use oak moss extract any more (SCCP, 2004), as it contains the most potent allergens chloroatranol and atranol (Johansen et al., 2003). IFRA limited the concentration of oak moss in deodorants to 0.03%. According to my study, nearly all producers followed this recommendation and use oak moss – if at all – at concentrations below 0.001%.

The increase of fragrances in my samples from 2008 to 2010 respectively 2011 might be explained by the fact that producers reduced their efforts to omit fragrances that need labeling since. The lower presence of fragrances in my sample raised in 2008 could also be due to a bias in the sample selection due to the small number or due to the fact that only products from four companies were analyzed. These results show how important it is to observe the product labeling over several years.

Lifelong application and personal exposure

Exposure of consumers depends on the type of product: As deodorants are directly applied to the skin of armpits, the major exposure route is dermal uptake. Ingredients of deodorant sprays can enter the human body also via inhalation. The quantitative exposures are relevant as there is a dose response relationship in persons sensitive to a certain fragrance (Bruze et al., 2003, 2005; Jorgensen et al., 2007; Svedman et al., 2003).

Personal exposure depends also to a large extent on the consumer behavior. Lorenz et al. (2011) described different detailed scenarios for the German population which showed very big differences between the personal application patterns of cosmetic products. 13.1% of adult males and 9.5% of adult females never use deodorants, while 31.5% of female teenagers use deodorants several times per day. If the frequency of application is high, deodorants can lead to high exposure levels, because the retention factor of deodorants is 1. Upper levels of fragrance incorporation in the skin by deodorants are estimated to be 1% (Cadby et al., 2002b).

The standard application daily dose of deodorants is between 1.5 g for deodorant non-spray and 0.69 g for deodorant spray non-ethanol based (SCCS, 2010). This amounts to between 20,000 and 45,000 t per year for 82 million inhabitants in Germany. The fragrance content is up to 3% in roll-on deodorants and up to 5%

in deodorant sprays (www.gmb.ikw.org). With these numbers the estimated total amount of fragrances applied through deodorants on the German population would be around 1000 t per year.

The Cosmetic Regulation sets up maximum threshold values in the final products for some of the strong allergens belonging to Group I: e.g. for hydroxycitronellal (1%), oak moss extract (0.1%) or isoeugenol (e.g. 0.02% for deodorants), but not for all “26 allergens”, e.g. not for Lyrall.

Rastogi et al. (2007a) made a quantitative chemical analysis of the “26 allergens” in 23 deodorants purchased in Denmark and published the contents for each deodorant. Highest concentrations were found for limonene with 11,386.5 µg/ml (=1.14 mass %) and citronellol with 5847.5 µg/ml (=0.58 mass %). The highest concentrations for strong allergens were found for Lyrall with 4431.0 µg/ml (=0.44 mass %), hydroxycitronellal with 1746.5 µg/ml (=0.17 mass %) and farnesol with 1791.0 µg/ml (=0.18 mass %). The highest concentration of isoeugenol was 138.4 µg/ml (=0.01 mass %) which is in the concentration range between 0.0063% and 0.2% that elicit axillary dermatitis in patients with contact allergy to isoeugenol (Bruze et al., 2005).

When I compare these quantitative determinations of the predominant fragrances with the frequency of occurrence on the labels, it turns out, that the fragrances identified most often on ingredient labels were also detected at larger amounts in products. This means that the exposure to these compounds exceeds other compounds twofold as the frequency of occurrence as well as the relative concentration in the products is higher.

The maximum amount of all “26 allergens” detected by Rastogi et al. (2007a) in a single deodorant was 23,578 µg/ml (=2.36 mass %), without considering other fragrances not labeled. 3–5% for perfume is in accordance with the content given by the frame formulation in the information sheets (“Gruppenmerkblätter”) of the IKW (www.gmb.ikw.org) and the cosmetic frame formulations (EAPCCT/COLIPA, 2000), but is more than the typical perfume level of 1% in deodorants given by Cadby et al. (2002b).

Fragrances are not only present in deodorants, but also in other cosmetic products, washing and cleansing products, food and further every day products (Wijnhoven et al., 2008). Exposure in everyday life might still be considerable, even if the concentrations in cosmetic products stay below the threshold values for labeling. The calculation of the exposure should consider all sources (Park et al., 2006; Wijnhoven et al., 2008).

Fragrances for sensitive skin

According to the new Regulation on Cosmetic Products (EC, 2009; Preamble (51) and Art. 20(1)) “the consumer should be protected from misleading claims concerning efficacy and other characteristics of cosmetic products.” If deodorants contain strong allergens above the labeling threshold, the words “sensitive”, “soft” or “skin soothing” (“hautberuhigend”) on the containers (Fig. 1) are misleading. Fragrances other than the 26 supposed allergens are subsumed under “parfum” on the list of ingredients. It cannot be ruled out that further allergens are among them. Nardelli et al. (2011) identified 30 relevant fragrances, among them 18 from the list of “26 allergens” and 12 additional candidates.

“Fragrance free” does not mean “free of fragrances”. In a survey among patients with contact allergy to fragrances, 72.6% indicated that they had used unscented deodorants in the past three months and 4.7% got a rash from it (Lysdal and Johansen, 2009). As the “26 allergens” need not be labeled if they are present below the threshold for labeling, it seems to be plausible that some patients might react to these products. It was shown, that isoeugenol can elicit symptoms at concentrations below 0.001%, the threshold for labeling in deodorants (Bruze et al., 2005). In addition, fragrance ingredients which serve other purposes such as preservative (e.g.

benzyl alcohol), antiseptic (e.g. hydroxycitronellal), solvent (e.g. benzyl benzoate) or aroma (e.g. citral, cinnamal, cinnamic alcohol, eugenol) may be employed in these products without labeling. The situation is complicated: combined exposure of an allergen with a detergent, e.g. in washing liquids can increase the allergic reaction (Heydorn et al., 2003), oral ingestion of fragrances as flavoring agents in food might influence the tolerance to contact allergens (White et al., 2009), and various fragrance substances show cross-reactions to each other.

Finding deodorants without the respective fragrance allergens is not easy for allergic consumers (Lysdal and Johansen, 2009). The German Allergy and Asthma Association (Deutscher Allergie- und Asthmabund, DAAB) recommends cosmetics and washing and cleansing products for its members. Among the cosmetic products recommended is one single deodorant, which is a deodorant spray free of fragrances, colorants and preservatives.

Conclusions and recommendations

Compulsory labeling does not lead to omission of strong allergenic fragrances in deodorants

The results of my analysis emphasize that the deodorants available at the retail sale do not guarantee the expected protection of consumers. The cosmetics industry takes over more responsibility for the use of allergenic fragrances by “the 26 allergens rule” than producers of other products where no labeling is required. Stricter rules in cosmetics are reasonable as many of them are used and applied to the body surface daily. But the question must be allowed: what were the intentions of the “26 allergen rule” and what is the outcome since it came into force? I outline three simple scenarios:

- (a) “If producers considered the label as a “stigma” for their products, they would reduce the amounts of the respective ingredients below the threshold values to avoid labeling.”

The composition of perfumes seems to have changed with the knowledge about allergenic fragrances (Rastogi et al., 2003, 2007b) and the concentrations and frequency of strong allergens seems to have gone down (Table 3). The fragrance industry took action and a few manufacturers produce deodorants where no perfume or fragrance is listed (1% in 2011, Table 1), but the majority of deodorants still contains the “26 allergens” (83% in 2011, Table 1).

- (b) “If consumers changed their shopping preferences and bought preferentially products, where the respective allergenic fragrances are not listed, manufacturers would be inclined to react and adapt the product compositions to the demand. Whereas if the consumers bought cosmetic products irrespective of the declarations on the containers, manufacturers would not have to change the product compositions as far as these 26 substances are concerned.”

Apparently, manufacturers changed the recipes of deodorants, but it is difficult to say whether this is due to the consumer behavior, to the responsible action of producers or to other reasons. Hardly any non-allergic consumer is aware of the “26 allergen rule”, according to inquiries among students at my university. Other criteria are more relevant to them when they choose a cosmetic product. Apparently, most consumers buy these products even if strong allergens are listed on the containers. The group of allergic patients has certainly contributed to a certain supply of cosmetic products with less allergens, but the mass market does not seem to have been affected. Comparison with the data by Rastogi et al. (1998), measured before the “26 allergen rule” came into force, might indicate that the number of deodorants containing certain compounds of the “26 allergens”

decreased to some extent, but as my data show the need for declaration does apparently not lead to their complete omission or to their reduction below the level requiring labeling.

- (c) “If fragrance sensitive persons are informed by compulsory labeling, they can avoid their sensitizers and the compositions of products need not necessarily change.”

Even patients who suffer from contact allergy do not use the information on the ingredient list to a large extent. In a survey among contact allergic patients 80% of the respondents indicated to read the ingredient lists of cosmetics, and 35.6% look whether certain fragrance ingredients are specified. Patients tend to try out which products they could tolerate (55.7%), rather than reading the ingredient lists (35.4%) (Lysdal and Johansen, 2009). As explained above in the discussion, various legally correct possibilities allow that an allergenic fragrance ingredient is in the product, but not listed on the container. The “26 allergen rule” does not help patients to avoid a certain ingredient completely.

The outcome of the three scenarios is not very satisfying with regard to consumer protection, but the design of the “26 allergen rule” did not strive for more.

The data collected here and in other studies (e.g. Klaschka, 2010; Noiesen et al., 2007; Rastogi et al., 2007a; Schnuch et al., 2007b) are not sufficient to show whether or to what extent improvements for the protection of the consumers were achieved by this labeling effort. A quantitative chemical analysis of ALL allergenic ingredients would be needed to know the true allergenic potential of deodorants together with the clinical studies of patients with single fragrances or the consumers' own cosmetic products. As such a study would be too comprehensive and hardly feasible, clinical studies may reflect the outcome of the risk management by the “26 allergens rule”. The number of people suffering from contact allergy did not go down, but rather follows fluctuating trends for the various fragrance compounds, for example in Belgium over the years 1990–2005 and 2000–2009 (Nardelli et al., 2008, 2011). Some of the 26 allergenic fragrances might have been substituted by other allergenic compounds. The frequency of contact allergy to isoeugenol seems to have increased in the UK (White et al., 2007), possibly due to the increased use of isoeugenol derivatives as substitutes which need not be labeled. While the number of patients allergic to Fragrance Mix I decreased, the number allergic to Fragrance Mix II and to other fragrances went up (Schnuch et al., 2004; Frosch et al., 2002, 2005a,b; Uter et al., 2010; Van Oosten et al., 2009). The results of patient screening for allergic contact dermatitis depend very much on the fragrances tested. “The more fragrance allergens (were) tested the more positive reactions can be observed” (Nardelli et al., 2008).

The regulation in the EU about skin sensitizers is better than in most other countries worldwide, but the situation is not satisfying. If the aim was to prevent development of allergies in non-sensitized persons and symptoms in sensitized patients, this risk management might not be successful.

Will the situation improve in future? According to the new EU Cosmetic Regulation the notification includes (Art. 13) information about nanomaterials (f), “the name and the CAS or EC number of substances classified as carcinogenic, mutagenic or toxic for reproduction” (g) and “the frame formulation for prompt and appropriate medical treatment in the event of difficulties.” (h), it does apparently not include the cosmetic product safety report, which would contain the qualitative and quantitative composition. Allergenic substances or other hazardous substances are not explicitly mentioned. Will this information be sufficient for local authorities and poison centers? Potential improvements with the new European chemical legislation were discussed in Klaschka (2010). It might be assumed that the strategy proposed by Jansson

Box 1: Recommendations (detailed explanations see also Klaschka, 2010).

For legislation:

- The “26 allergen rule” should be revised:
The ingredient lists on the product should contain information about all known fragrance ingredients and other sensitizers. For some fragrances shorter names that are easier to remember should be used (see SCCNFP, 2004) and the ingredient lists on the containers should be better readable. Substitutes of the “26 allergens” must be less hazardous. The list of 26 single substances should be replaced by criteria applicable to all candidates. Products containing potential allergens should bear a clearly understandable pictogram.
- Maximum levels should be set up depending on the sensitization potentials and the use pattern. Maximum concentrations of all allergens should be lower in deodorants than in other products, as the skin of the axilla is more sensitive (Bruze et al., 2005; Johansen et al., 1998). As long as they are not prohibited, products containing hazardous ingredients should be marked with a clear warning signal with description of the potential effects (e.g. for sensitizers) (such as on tobacco product containers in the EU).
- For an even better risk reduction, strong allergens and other ingredients with other hazardous effects should be banned from consumer products.
- Recommendations by SCCP/SCCNFP or IFRA should be examined and the outcome taken over in legislation.
- Cosmetic products should not be exempt from classification and labeling of hazardous substances.
- Regulations should be based on scientific results and on comprehensive risk assessments including health and environmental aspects and not on one single end point only.
- Information about the constituents of cosmetic products should be shared openly (not on demand) with poison centers, dermatologists, authorities and the general public.

For producers:

- The national and European regulations, the recommendation by the SCCS (previously SCCNFP and SCCP) and by IFRA should be observed.
- Products should be improved further and made less hazardous for human health and the environment.
- More unscented cosmetic products and products with less allergenic agents should be available on the market at reasonable prices.

Advice for consumers:

- Remember that fragrances can be sensitizing or toxic culprits in every day products.
- Avoid products that contain strong allergens or apply less.
- Close containers after use to keep the amount of oxidation in products lower.
- Do no longer use products one year after opening.

and Lodén (2001) would be more appropriate. They suggest to limit the concentration of fragrance in products, and to limit the concentration of well-known sensitizing fragrance chemicals.

Lessons learnt for nanomaterials

Expert groups are elaborating criteria for labeling products containing nanomaterials as risk reduction strategy or as a preliminary strategy until we know more about their concrete risks. It would be very useful for them to learn from “the 26 allergen rule”. The experiences made here question whether labeling alone is a

suitable way for risk management. Such a regulation depends on the very active role of the consumers and can only work if the majority of consumers are capable and willing to decide autonomously. They need sufficient knowledge about the science and the legislation, time to keep informed and interest to spend part of their lifetime on rather complicated issues. If they do not take over their power and do not refuse products which might be critical for their health or the environment, neither the amount of hazardous compounds in products nor the exposure does necessarily decrease. In addition, compulsory labeling needs to be controlled by the authorities, which demands a very high effort, as the product spectrum changes quickly (around 20,000 new or modified cosmetic products enter the German market every year; Butschke and Droß, 2010), the number of substances to be analyzed is high and the analytical determinations are expensive. The objectives of such a labeling strategy would have to be clearly defined and scrutinized after some years to see whether the goals were achieved or other procedures would be preferential.

Need for improvements

The regulation of a few substances due to their potency for skin sensitization creates a sort of pseudo-safety. Fragrance ingredients in deodorants may pose a considerable risk to consumers. They can provoke sensitization or induce symptoms in allergic patients, even if they comply with the actual legal requirements. “The 26 allergens rule” has many drawbacks and needs revision and improvement. The data and arguments in this article are meant to support the revision process as they demonstrate that other solutions would be more purposive for risk management than “the 26 allergens rule”. The main recommendations are summarized in Box 1. The sensitive skin of the human axilla deserves the most diligent treatment. Deodorants should be free of irritants and allergens.

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