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Review

European consumer exposure to cosmetic products, a framework for conducting population exposure assessments

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Abstract

Access to reliable exposure data is essential to evaluate the toxicological safety of ingredients in cosmetic products. This study was carried out by European cosmetic manufacturers acting within the trade association Colipa, with the aim to construct a probabilistic European population model of exposure. The study updates, in distribution form, the current exposure data on daily quantities of six cosmetic products. Data were collected using a combination of market information databases and a controlled product use study. In total 44,100 households and 18,057 individual consumers in five European countries provided data using their own products. All product use occasions were recorded, including those outside of home. The raw data were analysed using Monte Carlo simulation and a European Statistical Population Model of exposure was constructed. A significant finding was an inverse correlation between frequency of product use and quantity used per application for body lotion, facial moisturiser, toothpaste and shampoo. Thus it is not appropriate to calculate daily exposure to these products by multiplying the maximum frequency value by the maximum quantity per event value. The results largely confirm the exposure parameters currently used by the cosmetic industry. Design of this study could serve as a model for future assessments of population exposure to chemicals in products other than cosmetics.

Keywords: Cosmetics; Exposure; Probabilistic analysis; Monte Carlo; Statistical population modelling

Contents

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1. Introduction

Toxicological risk assessment, a central theme in the control of chemicals, is the scientific foundation of many national and international regulatory actions and exposure considerations are fundamental to this process. A number of activities have been initiated in the recent years with the aim of improving the methodology by which consumer exposure to chemicals is assessed (RIVM ConsExpo: www.rivm.nl/consexpo; ECETOC TRA Tool: http://www.ecetoc-tra.org; US EPA Center for Exposure Assessment Modelling: www.epa.gov, HealthCanada ComET model: http://www.thelifelinegroup.org). In Europe, evaluation of consumer exposure to chemicals has received particular attention in the run-up to the new REACH legislation (Registration, Evaluation, Authorisation of Chemicals, http://ec.europa.eu/chemicals/reach.htm). Scientifically sound exposure data are fundamental also to other areas currently of interest in risk assessment, such as the Threshold of Toxicological Concern (TTC) (Kroes et al., 2004) or risk assessment of acrylamide in food (Dybing et al., 2005). However, assessing exposure of populations, be it to consumer products or to food, is difficult not least because the studied sample should be large and representative of the population in question and also because of the natural, inter-individual variability inherent in the habits of consumers (Wormuth et al., 2005). The regulatory process may cope with this second problem by applying one of the two methods: the worst-case scenario or a probabilistic evaluation. The former involves setting exposure factors (daily use frequency and the amount per use) to worst case values and multiplying the two single numbers, thus arriving at a point exposure value. The latter, the approach taken in this study, multiplies two distributions, reflecting the uncertainty (variability) in the daily frequency and the amount per use, respectively. The Monte Carlo probabilistic method draws a large number of pairs of values from the two distributions, multiplies the two values in each pair and pools the resulting list of multiplication products into a histogram. This histogram gives the required uncertainty distribution (reflection of the variability in the population) for the daily exposure (amount in g). From this output distribution an appropriate percentile value is selected for the risk assessment (Kroes et al., 2002).

This study was carried out in 2004–2005 by European cosmetic manufacturers, acting within Colipa (The European Cosmetic,Toiletry and Perfumery Association, http://www.colipa.com). The aim was to update the currently used data (SCCP, 2006), already some 15 years old, and to provide new quantitative information on habits and practices of cosmetic product use in the European Union, referred here to as EU15 (reflecting the fact that the study was put into place in the year 2003, before the Union's enlargement). The study utilised the most up-to-date investigative methods of tracking consumer habits and the latest information technology methods, including statistical population modeling.

The objective of the present study was to provide robust data on the distributions of daily frequency (number of uses per day) and daily quantity of use of cosmetic products (amount per use in g), in order to produce distribution curves of daily exposure to these products (amount per day in g), in representative European countries, using Monte Carlo analysis. As stated above, the use of these distribution curves provides greater insight into the habits of the general population than do arbitrary point estimates: distributions reflect the inter-individual variations in the daily

frequency and amounts of products used, thus creating population exposure scenarios that are closer to real-life.

However, the implementation of this distribution-based approach requires data on both daily frequency of product use and amount of product used per event (per single application), obtained from a large sample (several thousands) of product users. Such data are not currently available and logistically impossible to obtain from a single source. In order to obtain exposure distributions, the combination of databases of varying sizes and from a number of different sources was used and a Monte Carlo simulation, using the amalgamated dataset, was carried out. A detailed description of the simulation and modeling methodology used in this study is provided in McNamara et al. (2007).

2. Materials and methods

The overriding principle of this study was to evaluate exposure to cosmetic products with the minimum disturbance to the study subjects' lives and routines. The significance of this principle for the study's quality and details of how this was achieved, are presented in the following parts of this publication. Pertinent to this section is the fact that in this study products were not offered to the subjects. All the study participants used their own products, according to their personal habits. As a result, the study covers a wide range of product brands.

2.1. Test products

All the test products were cosmetics. Taken together, they constitute more than half of the currently estimated daily exposure to cosmetic products in Europe (SCCP, 2006) and cover the majority of the parts of the body on which cosmetics are used. They were also selected to:

- Represent typical cosmetic exposure routes and duration (Table 1).
- Represent commonly used cosmetic products with important market penetration.
- Represent, as far as possible, products used by males and females.
- Represent products intended to be used daily.

2.2. Countries of investigation

The investigation was carried out in Denmark, France, Germany, Great Britain (GB) and Spain. These five countries were selected to represent a geographical cross-section of the European Union, referred to as EU15, reflecting the fact that the study was set up before the Union's enlargement. Denmark was chosen to represent northern Europe and Spain was chosen to represent southern Europe. Another country selection criterion was the size of the country's cosmetic market, to ensure that exposure was studied in pertinent locations. Thus four of the countries, France, Germany, GB, and Spain are commonly referred to as part of the 'BIG 5' European cosmetic and toiletry markets, which also includes Italy (not included in this study). Sales volumes of all product categories chosen for this study (the annual amount of each product sold), divided by the number of individuals using this product in the population, yielded amounts judged by the study's principal investigator (Taylor Nelson Sofres – TNS) to be sufficiently high to provide robust and reliable data to study exposure of the investigated populations. Spain, rather than Italy, was selected to represent southern Europe for the following reasons: sales of the cosmetic products, chosen by Colipa for the study, were higher in Spain than in Italy, the study consumer panel was larger in Spain and the data collection method in Spain, unlike that in Italy, was the same as in the other four countries in the Colipa study.

2.3. Data sources – study input

The primary database in this study is the TNS-European Toiletries and Cosmetics database (referred to as ETCD database). In order to generate exposure distributions in terms of *quantity* and *frequency* of product used per day, the ETCD database has been supplemented by two other databases: the Ian Smith Consultancy (ISC) and the TNS-Europanel databases. The following sections provide details of the databases used and the manner in which the data were collected.

2.3.1. European Toiletries and Cosmetics Database (ETCD)

The TNS European Toiletries and Cosmetics Database (TNS-ETCD, http://www.tns-global.com/uk/etcdneeds), operated and maintained by Taylor Nelson Sofres, is Europe's largest database providing continuous information on the habits and practices of consumers who use all the major toiletries and cosmetics categories in France, Germany, GB, Germany, Spain and Italy. For the purposes of this study, the existing data were obtained from the ETCD database for France, Germany, GB and Spain and a special study was set up by the TNS in Denmark.

ETCD records the daily *frequency* of use of cosmetic products through a postal survey consisting of a self-completion paper diary and questionnaire. The diary and questionnaire collect data on the toiletry and cosmetic products and brands that consumers use, how often they use them, where they apply the products (parts of the body and location when used) and the reasons for use. The diary and questionnaires are sent out to the same panellists once every six months and the diaries are completed over a period of one week. TNS-ETCD experience, based on their comparative study period data, indicate that one week is the optimum period during which the information provided by their panellists can be regarded as reliable.

In an average week 330 diaries are in circulation in the five countries covered by TNS. Diaries are completed for all weeks of the year. The

Table 1
List of tested products

Product	Exposure route	Application site	Exposure type
Body lotion	Dermal	Whole body	Leave-on
Deodorant/antiperspirant[a] spray	Dermal/inhalation	Axilla	Leave-on
Deodorant/antiperspirant[a] non-spray	Dermal	Axilla	Leave-on
Lipstick	Oral/dermal	Perioral, mucous membranes	Leave-on
Facial moisturiser	Dermal	Face, periocular	Leave-on
Shampoo	Dermal	Scalp, neck, hands	Rinse-off
Toothpaste	Oral/dermal	Perioral, mucous membranes	Rinse-off

In the case of the Deo/AP spray, the data provided by the present study is the information on the quantity of the product leaving the can during use. Quantification of dermal and inhalation exposure to a product of this type will require further investigation.

[a] These products will be referred to as "Deo/AP spray" or "Deo/AP non-spray".

completed diaries and questionnaires from all countries are returned to TNS where they are collated and scanned to produce an aggregated database for analysis.

The ETCD is a *weighted* database. This means that each subject entry in the database comes with a numerical weight attached, indicating the proportion of demographically similar subjects in the whole population. ETCD has collected data using this method since 1995.

In each country the study inclusion criteria were as follows: Females and males (ratio 70–30%), age 17–74 years, sample representative of the region, working status and age, habitual users of all products, brands and categories for toiletries and cosmetics. In total data from 17,561 volunteers were obtained.

The ETCD database provided distribution curves of daily *frequency* of use of each product, in each of the studied countries, during one year. However, the ETCD does not contain the information on the quantity of product used per application. These data were obtained with the aid of two other databases, as described below.

2.3.2. ISC database

The ISC Clinical Research Organisation used to be a company located in the Edinburgh area of Scotland. It has closed down since the completion of this study, after 25 years of activity. Edinburgh was chosen as a cosmopolitan area covering many cultures and therefore considered to be representative of GB. The purpose of the ISC study was to collect data on *amounts* used per event for each cosmetic product. The criteria for volunteer selection used by ISC, including the demographic breakdown of the panellists, matched those of the ETCD.

Five hundred and two volunteers, age 17–74, all habitual users of the cosmetic products selected for the study, were recruited into the study and 496 completed the full two-week usage period. "Habitual user" was defined as at least once-a-month user of a given product. Another qualification for entry into the study was determined by the number of product types used by each panellist, i.e., a minimum of 4 out of 6 types (Deo/AP spray or non-spray count as one product type as consumers typically use one of the two) for female subjects and minimum of 3 out of 6 for male subjects. Great majority of the panellists in the ISC study (except some 15% who had to be especially recruited in order to complete the demographic breakdown of the panel) were habitual participants in clinical tests, many of which require regular diary completion, often over a period of several weeks. A two-week diary completion period was, therefore, within the reliability period of the panel in this type of test. All subjects signed a study information form and a volunteer consent form and all completing subjects confirmed, at the end of the study, by a signed questionnaire, that they were the sole users of the studied products. A two-week period of product use was the minimum judged necessary to obtain accurate product weight differences, especially for lipstick where the two-weeks' consumption ranged from 4.5 mg to 2.5 g.

Participants brought their own products to the test centre, where the study, with all its requirements and restrictions, was explained to them and where their products were weighed and labelled, out of panellists' sight, before commencement of the study. Each participant recorded each usage occasion in a diary throughout the two weeks' test period. The products were re-weighed at the end of the study, again out of panellists' sight. The panellists were, therefore, not aware that the quantity of product used was one of the researched parameters. This aspect of the study was important, as experience shows that this awareness tends to increase the quantity of product used (ISC personal communication). By dividing the total quantity of product used during the study period by the number of times the product was used (marked in the diary) the average amount of product per use per respondent, was obtained.

The ISC database provided distribution curves for the *amount* of product used per event.

2.3.3. TNS-Europanel database

TNS-Europanel (referred to as Europanel, http://www.europanel.com) is a continuous, all year round consumer panel, a joint venture owned by TNS and GfK (Gesellschaft für Konsumerforschung, http://www.gfk.com).

Europanel provide data on the number of products purchased by consumers per year (purchase panel information) in 40 European countries. Consumer panels are a sample of consumers selected to represent a target population in terms of their purchasing behaviour (in this case users of cosmetic products). Purchase panels continuously track toiletry and cosmetic purchases that are taken into their homes. Barcodes on all purchased products are scanned using a palm-held portable scanner and the panellists enter purchasing information, such as store type, day of week, etc., into the scanner. The resulting data are downloaded to a central database to be analysed. In this way Europanel provides data on total quantity sold by product category in a given year.

Forty-four thousand and one hundred households from the five selected countries provided purchasing information for this study.

Combination of the ETCD and Europanel databases allowed calculation of the expected quantity of product used per event, per country, as follows, e.g.:

In GB, during one year the Europanel recorded sales of 60 922 235 l of shampoo. In the same year the ETCD recorded 7 894 688 703 shampooing occasions. Dividing the volume sold by the number of shampooing occasions results in 7.7 ml of shampoo used per event in GB, assumed to be equivalent of 7.7 g.

These values, referred to as the Country Amount Used per Application (CAUA) are amount-per-event *point values* for each product in each country. CAUA values were obtained for each country and each product in this study. In order to obtain amount-per-event *distribution curves* for each country and each product, the CAUA values had to be combined with the amount-per-event distribution curves obtained from the ISC study, using Monte Carlo simulation, as described below.

2.4. Study timing

The Europanel and the ETCD data were collected over the period of one year (2003) from the consumers in the four countries (each of whom filled in the diary during one week) and from the Danish consumers – over the period of one week. The ISC study and the Denmark diary study were both carried out in the winter months (2004) following the year in which the ETCD and Europanel data were gathered. Both the TNS Denmark and the ISC data were assumed to be representative of an 'average week or fortnight' within a year (TNS information). According to the TNS database, there are no significant differences in consumer behaviour throughout the year that would affect the reliability of the data. In any case, the weeks the studies were carried out in Denmark and Scotland were chosen to avoid any coincidence with the Christmas or Easter holidays, where usage pattern may be temporarily affected.

2.5. Bodyweight data for the studied populations

Product usage data were supplemented with the bodyweight data. As no bodyweight information existed for the subjects in the ETCD database, this information had to be inputted as statistical values which represent the population of each country. The LogNormal distribution was used for bodyweights as this distribution is widely accepted to be suitable for bodyweight distributions (McNamara et al., 2007). Separate distribu-

Table 2
Bodyweight distributions for each country (means, standard deviations)

Country	Male	Female
ISC/Scotland	LogNormal(85.65, 16.68)	LogNormal(73.98, 16.93)
France	LogNormal (77.73, 13.48)	LogNormal (66.78, 12.71)
Germany	LogNormal (84.51, 13.48)	LogNormal (71.63, 12,71)
Spain	LogNormal (73.23, 13.48)	LogNormal (62.56, 12.71)
GB	LogNormal (80.00, 13.48)	LogNormal (67.30, 12.71)
Denmark	LogNormal (83.61, 13.48)	LogNormal (68.46, 12.71)

tions were used for males and females for each country using mean values form the ECETOC Exposure Factors Sourcebook (ECETOC, 2001), and the standard deviations were taken from Eurostat (2002). The values used are shown in Table 2.

2.6. Monte Carlo simulation – study output

The raw disaggregated data (ETCD, Europanel and the ISC databases) were combined by CREMe Ltd., (www.cremsoftware.com) who also performed the Monte Carlo simulation analysis, using their high performance computing tool CREMe. CREMe the "Central Risk and Exposure Modelling e-solution" is a web-based software solution that incorporates scientifically validated and peer reviewed models and utilises on-demand high performance computing. The CREMe tool specialises in the areas of population exposure assessment to consumer products (including cosmetics) and food chemicals.

The simulation methodology is briefly described here and the details are provided in McNamara et al. (2007).

An exposure modelling computer programme was used (Monte Carlo analysis), to produce a population distribution curves of daily amount-per-day exposure.

The outputs of the study were distribution curves for amount of product used per day (g/day) and amount of product used per day per kilogram of body weight (mg/day/kg bw).

The following are the steps in the construction of the European Statistical Population Model of consumer exposure to selected cosmetic products.

2.6.1. Frequency of product use per day distribution curves

The number of occasions of product use, recorded by each panellist in the ETCD database during 7 days, was divided by 7 to obtain data on average *frequency* per day of product use for each of the 17,561 study panellists in the five countries.

2.6.2. Amount-per-day distribution curves

2.6.2.1. ISC database. Real values for product usage *amounts* were obtained from the 496 volunteers in the ISC habits and practices study. The ISC volunteers were recruited on the basis of habitually using each of the studied products at least once a month, but only those who used a product at least once during the two-week study period were included as the study subjects for this product. The final breakdown of product users in the ISC study was as follows: Lipstick: 209 females (F); toothpaste: 307 F–142 males (M); Deo/AP non-aerosol: 144 F–32 M; Deo/AP aerosol: 198 F–125 M; shampoo: 331 F–141 M; body lotion: 243 F–14 M; facial moisturiser: 289 F–41 M. There were no "non-users" in this study and not every ISC participant used all of his/her products during the course of the two-weeks. The aim of this study was to provide the distribution curve of the amount of product used (in g) per event. The amount of product used was recorded over the period of 14 days. For each participant the total quantity of product used during the study was divided by the number of use occasions to obtain average amount used per event. These data were then extended to the five European countries in the study, by combining them with the Europanel and the ETCD databases, as described below.

2.6.2.2. Combining the databases to obtain the amount-per-use distribution curves for the five countries studied. The ISC database was used to generate *distributions* of the amount of product used per event and for each product. These distributions were then inserted into the ETCD frequency-of use database for GB, by assigning to each ETCD responder in a given frequency-of-use bracket, the amount value obtained from the ISC responder of matching demography and frequency of use. This updated version of the ETCD, after adjustment to the correct population gender ratio (from the 70% females and 30% males in the study), now contained information on both *frequency* of use per day and of *amount used per event*. This process required specialised software capable of generating random variates from input text strings, and of rapidly performing the above calculations on large databases (McNamara et al., 2007).

The mean ISC amount-per-use value for each product was then compared with the CAUA for GB to confirm that the ISC data were representative of GB. For Deo/AP non-spray, facial moisturiser, shampoo and toothpaste the ISC mean was higher than the national GB CAUA value, and as ISC was considered to represent GB (McNamara et al., 2007), these values were used as such with no scaling. For body lotion, lipstick and Deo/AP spray, the ISC mean was lower than the national GB CAUA value, and the distribution curves for these products were adjusted up, as in the following example:

Deo/AP spray average ISC-recorded usage (amount per use) was 1.727 g and the GB CAUA value was 3.27 g. In this case the scale factor of 1.894 (3.27/1.727) was used to scale up the distribution curves obtained in the ISC study to the quantity per application values recorded for GB by the Europanel database.

Note: In scaling up, the *shape* of the quantity distribution curves remained unchanged, only the quantity *values* were increased by the scaling factor of 1.894.

Corresponding scale factors were used for body lotion (1.085) and lipstick (2.56).

Amount-per-use distributions were then generated for the remaining four European countries. For these countries the scaling factor was always the CAUA divided by the ISC mean value, even if this ratio was less than 1 (McNamara et al., 2007). On the basis of the ETCD and Europanel data it was assumed in these cases that consumers in these countries used on average less product per application than the ISC population.

2.6.2.3. Amount-per-day distribution curves for the five countries studied. Monte Carlo analysis was then performed using CREMe software to multiply the frequency per day and amount per use distributions, in order to obtain a distribution of the exposure in terms of *amount per day* for each product, for each country:

$$\textit{Daily exposure}\ (\mathrm{g}) = \textit{average daily frequency of use} \times \textit{average amount of product used per event}\ (\mathrm{g}).$$

The simulation took into account any correlations found between frequency of use and amount used per event (McNamara et al., 2007).

2.6.2.4. Constructing the European Statistical Population Model. Finally, the country-based daily amount-per-use distributions were weighted according to population statistics, (EU census data) to produce representative daily exposure distributions for the total EU population (EU15). To achieve this, each country in the ETCD database was assumed to represent one or more EU countries with similar climate/cultural features. Thus, "Spain" represented Spain, Italy, Portugal and Greece (southern European countries), Great Britain ("GB") represented the UK and Ireland, "France" represented France, "Germany" was assumed to represent Germany, Belgium, Luxembourg, the Netherlands and Austria and "Denmark" represented Denmark, Finland and Sweden (northern European countries). Population data for the EU15 were then utilised to generate weighted sampling on the whole ETCD database, resulting in the generation of a database representative of EU15.

Thus an EU15-representative 30,000 subject population was constructed from the five countries' data sets, by weighting each country's population and using the subject selection model as described (McNamara et al., 2007).

The results per kilogram bodyweight were also produced by dividing the amount-per-day exposure for each subject by their bodyweight in kilograms at each iteration. The bodyweight for each subject was drawn from a lognormal distribution for males and females for each country.

The inputs and outputs of the study are summarised below (see Fig. 1).

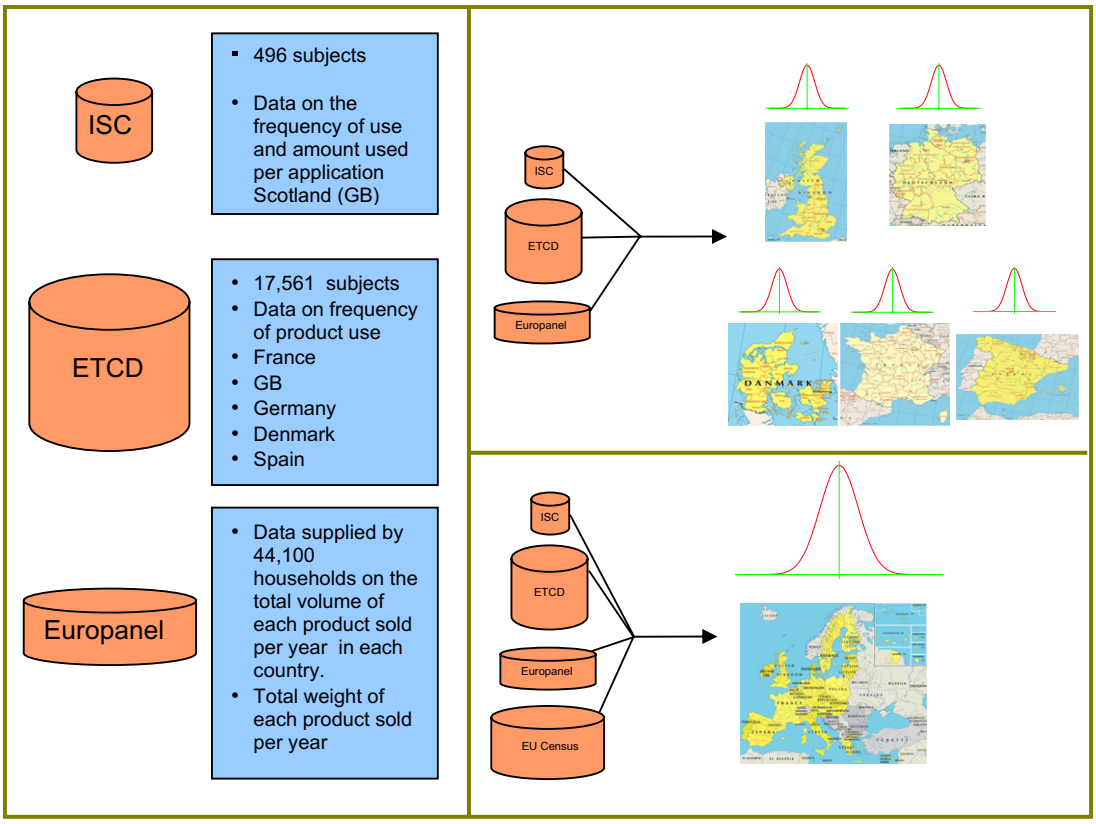


Fig. 1. Schematic diagram of study for each product.

2.6.3. Summary of the procedure leading to the estimate of population exposure

2.6.3.1. Construction of the statistical population model.

- Daily frequency of product use and amount used per event are the prerequisites for obtaining amount per day exposure distributions for cosmetic products.
- The ETCD is the main simulation database. It contains data on frequency but it lacks information on the amount of product used per event.
- The ISC database was needed to provide input distributions of the amount used per event for the ETCD.
- Each ETCD frequency-of-use responder was attributed an amount-per-use value obtained from an ISC responder of matched demography and frequency of use: an amount-per-use curve was constructed for the ETCD database.
- Europanel was used to scale input amount distributions from the local ISC values to the five countries studied.
- Whenever significant correlations were found between frequency of use and amount per use for test products, these correlations were taken into account when simulating and this affected the output exposure distributions.
- The data contained in the ETCD were used to generate representative populations for each country, and for the EU15. European exposure distributions were generated from these new databases.

2.7. Conservatism of the model

Particular care was taken not to underestimate the exposure. Thus the study design incorporated two conservative features: all products reported as sold in the Europanel database were assumed to have been used, which is not always the case in real life and the calculations assumed that Europe as a whole (EU15) behaved like the highest consuming country in our study, in terms of each product consumption. This was achieved by assigning, for the European population and for each product, the largest of the scale factors for each of the individual five countries of study (McNamara et al., 2007). For example, the calculated EU 15 exposure to Deo/AP spray was driven by the highest frequency of use of Deo/AP spray recorded in GB and UE15 exposure to shampoo was driven by the highest shampoo use recorded in Denmark.

3. Results

3.1. Effect of correlation

A significant new finding from this study, resulting from the analysis of the ISC database, is that for body lotion, facial moisturiser, toothpaste and shampoo there is an inverse correlation between the frequency of product use and the quantity used per event. This means that the more often a consumer uses any of these products the less product will be used on each occasion, i.e., the amount of product per use declines with frequency of use (for details see McNamara et al., 2007).

This is illustrated by an example from the ISC study on body lotion:

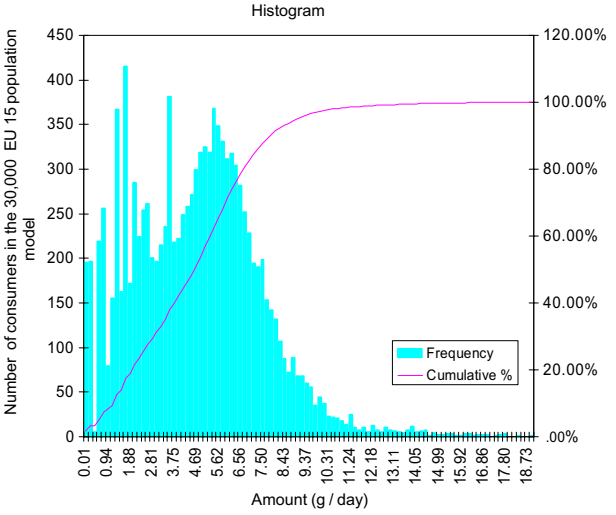
*Volunteer A:*75 uses/2 weeks, total product used = 68.15 g, mean amount/event = 0.91 g, mean amount/day = 4.87 g.

*Volunteer B:*15 uses/2weeks, total product used = 86.3 g, mean amount/event = 5.75 g, mean amount/day = 6.16 g.
*Volunteer C:*8 uses/2 weeks, total product used = 77.8 g, mean amount/event = 9.7 g, mean amount/day = 5.56 g.

No correlation was found between daily frequency of use and amount per use for lipstick and Deo/AP.

3.2. Daily exposure

Results are presented in the form of histograms relating amount of product used per day to the number of consumers in the 30 000 EU15 population model.



Value	Amount (g / day)	Stdev
mean	4.543	0.012
std	2.707	0.013
median	4.556	0.023
minimum	0.005	0.000
maximum	21.081	1.264
p01	0.005	0.000
p02.5	0.017	0.000
p05	0.556	0.008
p10	1.129	0.006
p20	1.948	0.018
p30	2.907	0.024
p40	3.737	0.027
p50	4.556	0.023
p60	5.246	0.023
p70	5.898	0.021
p80	6.645	0.024
p90	7.822	0.033
p92	8.183	0.038
p94	8.651	0.042
p95	8.951	0.047
p96	9.326	0.054
p97.5	10.191	0.081
p98	10.655	0.096
p99	12.261	0.155
p99.5	13.893	0.221
p99.9	16.991	0.413

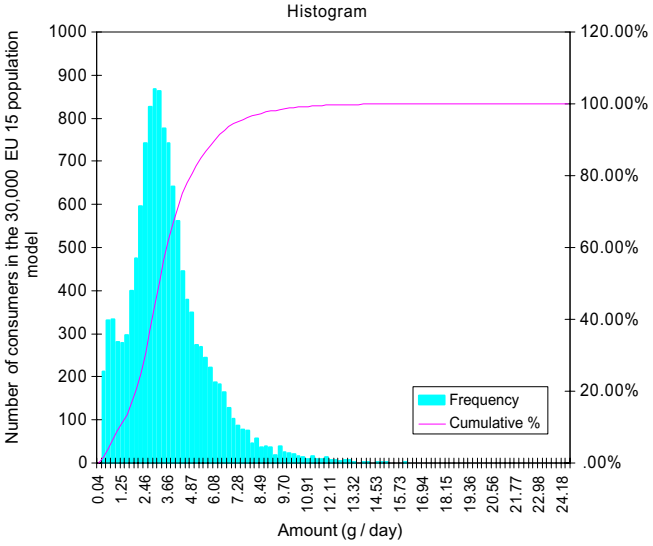
Value	Amount (mg / kg / day)	Stdev
mean	67.869	0.228
std	43.866	0.307
median	64.265	0.369
minimum	0.043	0.003
maximum	401.371	46.215
p01	0.079	0.003
p02.5	0.250	0.011
p05	8.066	0.191
p10	15.055	0.293
p20	27.535	0.330
p30	40.763	0.359
p40	53.072	0.357
p50	64.265	0.369
p60	75.114	0.374
p70	86.751	0.404
p80	101.024	0.495
p90	123.227	0.715
p92	130.177	0.868
p94	139.085	0.968
p95	144.797	1.072
p96	151.892	1.211
p97.5	167.036	1.559
p98	174.414	1.768
p99	198.018	2.888
p99.5	222.667	4.420
p99.9	282.959	10.304

Fig. 2. EU15 body lotion exposure histogram (g/day) for consumers only (males and females).

The values of a range of statistics and a range of percentiles are also shown in tables for each product, along with their variation over the iterations, expressed as standard deviation. The amount data are given in grams (g) in all cases, unless otherwise stated.

Exposure to each product is presented in g/day and mg/kg/day (see Figs. 2–9).

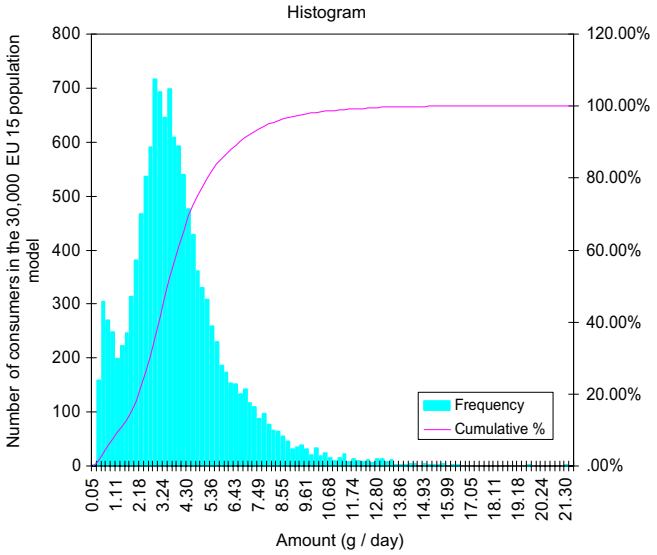
The Deo/AP Spray analysis was performed with input data from ISC for two sets of subject data. In the first case (Fig. 3) subjects who only used the product under the arms were considered. In the second case (Fig. 4) subjects who



Value	Amount (g / day)	Stdev
mean	3.478	0.007
std	2.051	0.009
median	3.153	0.012
minimum	0.045	0.005
maximum	23.663	1.724
p01	0.228	0.012
p02.5	0.373	0.008
p05	0.598	0.011
p10	1.135	0.014
p20	1.951	0.012
p30	2.425	0.010
p40	2.796	0.011
p50	3.153	0.012
p60	3.548	0.013
p70	4.049	0.015
p80	4.804	0.019
p90	6.095	0.029
p92	6.477	0.031
p94	6.955	0.037
p95	7.262	0.040
p96	7.645	0.047
p97.5	8.537	0.064
p98	9.005	0.076
p99	10.451	0.107
p99.5	11.628	0.132
p99.9	13.843	0.277

Value	Amount (mg / kg / day)	Stdev
mean	49.07	0.13
std	31.00	0.22
median	43.52	0.19
minimum	0.59	0.10
maximum	379.03	63.23
p01	3.08	0.13
p02.5	5.08	0.12
p05	8.23	0.16
p10	15.31	0.20
p20	25.75	0.17
p30	32.38	0.17
p40	37.96	0.17
p50	43.52	0.19
p60	49.73	0.22
p70	57.50	0.27
p80	68.59	0.32
p90	87.79	0.49
p92	93.94	0.58
p94	101.93	0.71
p95	107.01	0.81
p96	113.29	0.91
p97.5	126.91	1.24
p98	133.46	1.40
p99	154.31	1.98
p99.5	175.01	2.80
p99.9	222.53	7.29

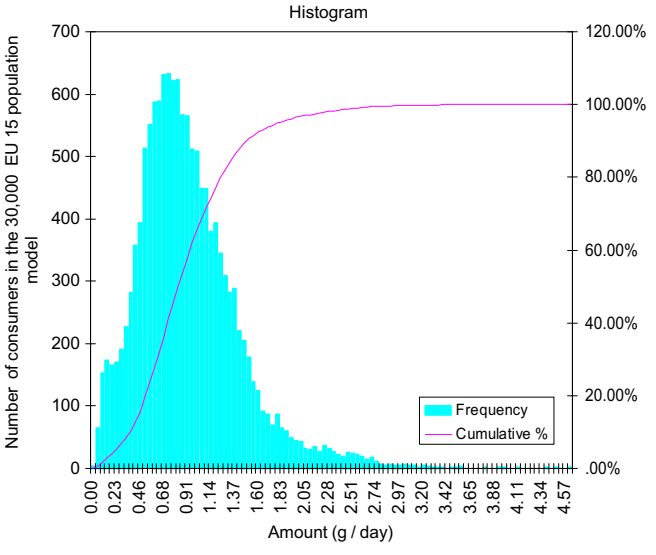
Fig. 3. EU15 Deo/AP spray exposure (g/day) for consumers only (males and females) – under arms use only.



Value	Amount (g / day)	Stdev
mean	3.732	0.008
std	2.213	0.010
median	3.383	0.012
minimum	0.044	0.005
maximum	24.662	2.057
p01	0.239	0.014
p02.5	0.384	0.009
p05	0.639	0.015
p10	1.214	0.015
p20	2.078	0.013
p30	2.580	0.012
p40	2.986	0.011
p50	3.383	0.012
p60	3.819	0.014
p70	4.364	0.016
p80	5.156	0.021
p90	6.543	0.030
p92	6.969	0.036
p94	7.505	0.042
p95	7.839	0.048
p96	8.263	0.053
p97.5	9.213	0.069
p98	9.711	0.080
p99	11.263	0.117
p99.5	12.544	0.157
p99.9	14.898	0.300

Value	Amount (mg / kg / day)	Stdev
mean	52.47	0.14
std	32.94	0.23
median	46.66	0.20
minimum	0.59	0.10
maximum	389.12	66.91
p01	3.19	0.14
p02.5	5.30	0.15
p05	8.80	0.18
p10	16.47	0.23
p20	27.71	0.18
p30	34.76	0.17
p40	40.73	0.18
p50	46.66	0.20
p60	53.26	0.21
p70	61.50	0.27
p80	73.25	0.35
p90	93.70	0.53
p92	100.24	0.60
p94	108.70	0.73
p95	114.08	0.81
p96	120.73	0.92
p97.5	135.17	1.24
p98	142.13	1.42
p99	164.14	2.31
p99.5	186.13	3.14
p99.9	235.47	7.01

Fig. 4. EU15 Deo/AP spray exposure (g/day) for consumers only (males and females) using product over torso and under arms



Value	Amount (g / day)	Stdev
mean	0.898	0.002
std	0.494	0.002
median	0.820	0.003
minimum	0.000	0.000
maximum	4.528	0.300
p01	0.064	0.002
p02.5	0.123	0.004
p05	0.221	0.004
p10	0.363	0.003
p20	0.509	0.003
p30	0.617	0.003
p40	0.718	0.003
p50	0.820	0.003
p60	0.934	0.004
p70	1.068	0.004
p80	1.238	0.005
p90	1.509	0.007
p92	1.598	0.008
p94	1.722	0.010
p95	1.806	0.011
p96	1.912	0.013
p97.5	2.134	0.016
p98	2.233	0.017
p99	2.515	0.025
p99.5	2.771	0.033
p99.9	3.426	0.088

Value	Amount (mg / kg / day)	Stdev
mean	12.95	0.04
std	7.34	0.05
median	11.77	0.05
minimum	0.00	0.00
maximum	73.91	7.48
p01	0.90	0.04
p02.5	1.75	0.05
p05	3.12	0.06
p10	5.08	0.05
p20	7.26	0.05
p30	8.85	0.05
p40	10.30	0.05
p50	11.77	0.05
p60	13.36	0.05
p70	15.25	0.07
p80	17.77	0.08
p90	22.08	0.12
p92	23.51	0.14
p94	25.37	0.17
p95	26.57	0.19
p96	28.05	0.21
p97.5	31.18	0.28
p98	32.67	0.32
p99	37.25	0.48
p99.5	41.93	0.72
p99.9	52.79	1.63

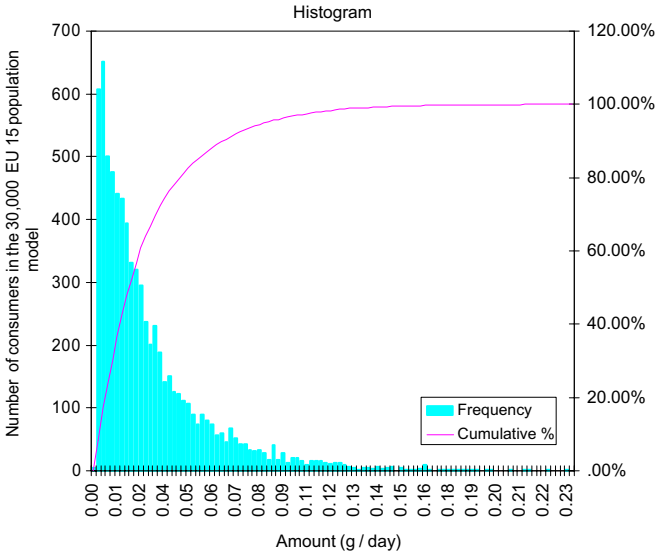
Fig. 5. EU15 Deo/AP non-spray exposure (g/day) for consumers only (males and females).

used the product anywhere on the body were considered (this set also included the users who used it under the arms only). There were 14 people (4.3% of the 323 volunteers who used the Deo/AP Spray) in the second set.

4. Discussion

The widespread use of cosmetic products and the variability of habits and practices of consumers are the chief difficulties in an accurate evaluation of consumer exposure to cosmetics. Especially, when setting out to conduct a realistic exposure study on the scale of a population, the traditional method of giving products to volunteers, recording the number of uses and the total quantity used, is no longer adequate. A study on such a scale calls for use of new evaluation tools. These were employed in this study resulting in the construction of the European Statistical Population Model of exposure to selected cosmetic products.

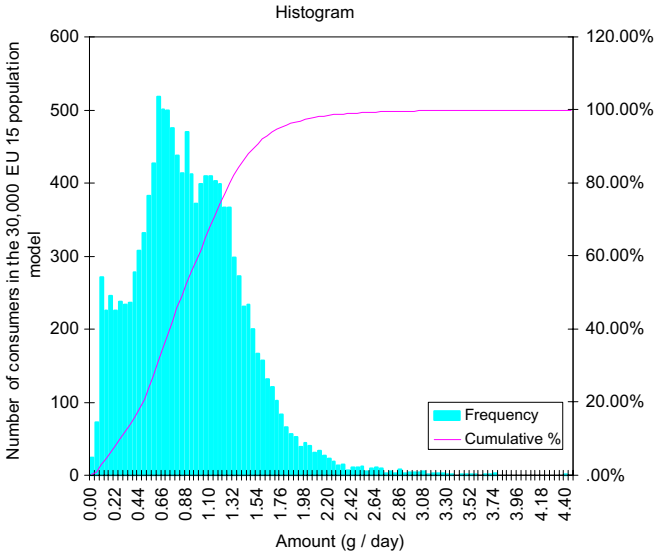
The innovation of this study was to combine rigorous market information data with data from a controlled, own product-use test and use of a Monte Carlo simulation,



Value	Amount (mg / day)	Stdev
mean	24.61	0.17
std	24.05	0.25
median	17.11	0.18
minimum	0.13	0.04
maximum	217.53	26.01
p01	0.57	0.04
p02.5	1.00	0.07
p05	1.68	0.07
p10	2.95	0.07
p20	5.69	0.11
p30	9.20	0.14
p40	12.93	0.15
p50	17.11	0.18
p60	22.37	0.24
p70	29.43	0.33
p80	39.70	0.47
p90	56.53	0.66
p92	61.66	0.72
p94	68.29	0.86
p95	72.51	0.95
p96	77.78	1.08
p97.5	89.08	1.34
p98	94.46	1.52
p99	110.98	2.06
p99.5	126.71	2.93
p99.9	160.06	6.33

Value	Amount (mg / kg / day)	Stdev
mean	0.39	0.00
std	0.40	0.01
median	0.26	0.00
minimum	0.00	0.00
maximum	3.88	0.55
p01	0.01	0.00
p02.5	0.02	0.00
p05	0.03	0.00
p10	0.04	0.00
p20	0.09	0.00
p30	0.14	0.00
p40	0.20	0.00
p50	0.26	0.00
p60	0.34	0.00
p70	0.46	0.01
p80	0.62	0.01
p90	0.90	0.01
p92	0.98	0.01
p94	1.10	0.02
p95	1.17	0.02
p96	1.26	0.02
p97.5	1.46	0.03
p98	1.55	0.03
p99	1.84	0.04
p99.5	2.13	0.06
p99.9	2.78	0.14

Fig. 6. EU15 lipstick exposure (g/day) for consumers only (females).



Value	Amount (g / day)	Stdev
mean	0.906	0.003
std	0.533	0.004
median	0.851	0.004
minimum	0.001	0.000
maximum	4.751	0.380
p01	0.055	0.002
p02.5	0.079	0.004
p05	0.138	0.001
p10	0.261	0.004
p20	0.472	0.004
p30	0.603	0.003
p40	0.721	0.003
p50	0.851	0.004
p60	0.990	0.004
p70	1.131	0.004
p80	1.289	0.005
p90	1.536	0.007
p92	1.617	0.008
p94	1.727	0.010
p95	1.801	0.012
p96	1.897	0.014
p97.5	2.129	0.022
p98	2.251	0.027
p99	2.653	0.043
p99.5	3.040	0.057
p99.9	3.714	0.108

Value	Amount (mg / kg / day)	Stdev
mean	13.62	0.05
std	8.63	0.08
median	12.42	0.06
minimum	0.02	0.00
maximum	92.75	11.80
p01	0.73	0.04
p02.5	1.13	0.03
p05	1.89	0.04
p10	3.67	0.06
p20	6.63	0.05
p30	8.66	0.05
p40	10.51	0.06
p50	12.42	0.06
p60	14.47	0.07
p70	16.78	0.07
p80	19.65	0.10
p90	24.14	0.14
p92	25.57	0.17
p94	27.46	0.19
p95	28.68	0.22
p96	30.23	0.25
p97.5	33.73	0.35
p98	35.52	0.43
p99	41.63	0.71
p99.5	48.23	1.08
p99.9	63.35	2.62

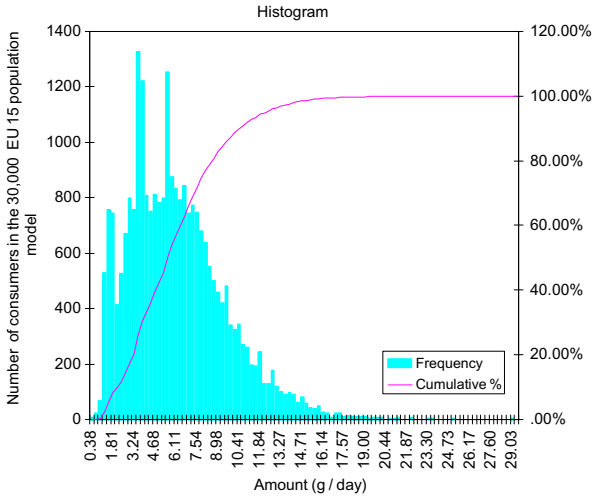
Fig. 7. EU15 facial moisturiser exposure (g/day) for consumers only (males and females).

using raw disaggregated data in order to avoid creating artifacts by forcing data into an inappropriate fit.

4.1. Innovative aspects of the study

The study features several innovative aspects:

- *Scope:* In total, data supplied by 44,100 households, and 18,057 (17,561 ETCD and 496 ISC) habitual users of the investigated cosmetic product types, were used to create a representative sample of the 248.5 million inhabitants of the 15 countries of the European Union (before the enlargement). Overall the study generated more than 250 000 pieces of individual data sets.
- *Data gathering method:* The most important aspect of this study was the fact that the cosmetic usage practices of the consumers who provided the data (the ETCD, the Europanel and the ISC volunteers) were investigated with a minimum disturbance to their daily habits of their own product use and that every attempt was made to record all the occasions when the investigated



Value	value (g/day)	stdev
mean	6.034	0.014
std	3.296	0.015
median	5.503	0.020
minimum	0.344	0.036
maximum	29.607	0.669
p01	1.071	0.000
p02.5	1.268	0.023
p05	1.482	0.024
p10	2.178	0.019
p20	3.236	0.016
p30	3.843	0.019
p40	4.777	0.023
p50	5.503	0.020
p60	6.416	0.022
p70	7.390	0.026
p80	8.597	0.028
p90	10.456	0.039
p92	11.013	0.054
p94	11.721	0.041
p95	12.181	0.063
p96	12.705	0.064
p97.5	13.765	0.073
p98	14.194	0.091
p99	15.637	0.110
p99.5	16.992	0.149
p99.9	20.397	0.443

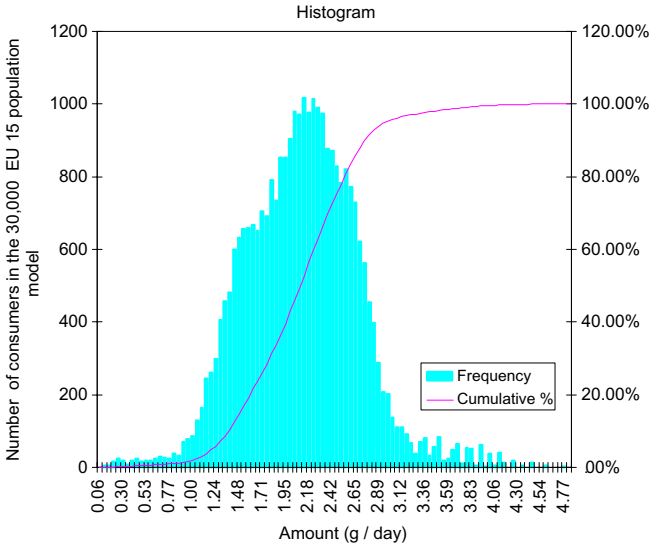
Value	value (mg/kg/day)	stdev
mean	85.888	0.223
std	48.992	0.278
median	77.895	0.294
minimum	3.826	0.461
maximum	528.361	65.887
p01	12.781	0.148
p02.5	16.367	0.181
p05	21.059	0.182
p10	29.737	0.269
p20	44.415	0.242
p30	55.58	0.253
p40	66.502	0.27
p50	77.895	0.294
p60	90.255	0.332
p70	104.537	0.373
p80	122.6	0.461
p90	150.488	0.642
p92	159.046	0.73
p94	169.939	0.846
p95	176.768	0.922
p96	185.092	1.08
p97.5	202.349	1.396
p98	210.49	1.551
p99	235.613	2.142
p99.5	260.624	3.009
p99.9	320.47	6.689

Fig. 8. EU15 shampoo exposure (g/day) for consumers only (males and females).

products were used, including those out-of-home. Even the diary filling was for these volunteers a normal, habitual event.

ETCD, the largest available database of European cosmetic product usage, can be considered to be the most appropriate source for the generation of frequency-of-use distributions for each product in each country of interest.

The advantages of the ETCD data collection methodology, in which the panellists record the brands and products they normally use in their daily routine, as opposed to a more traditional method of studying exposure i.e. providing the panellists with products especially selected for the study (Loretz et al., 2005), are the following:



Value	Amount (g / day)	Stdev
mean	2.092	0.001
std	0.577	0.001
median	2.101	0.003
minimum	0.069	0.012
maximum	4.969	0.159
p01	0.777	0.011
p02.5	1.049	0.006
p05	1.204	0.004
p10	1.370	0.003
p20	1.591	0.003
p30	1.790	0.003
p40	1.958	0.003
p50	2.101	0.003
p60	2.237	0.003
p70	2.383	0.003
p80	2.551	0.003
p90	2.749	0.003
p92	2.809	0.004
p94	2.895	0.005
p95	2.960	0.006
p96	3.052	0.008
p97.5	3.323	0.010
p98	3.447	0.015
p99	3.760	0.006
p99.5	3.956	0.026
p99.9	4.303	0.049

Value	Amount (mg / kg / day)	Stdev
mean	29.85	0.04
std	10.34	0.05
median	28.67	0.06
minimum	0.93	0.18
maximum	98.77	8.19
p01	10.14	0.14
p02.5	13.34	0.08
p05	15.47	0.06
p10	17.96	0.06
p20	21.29	0.05
p30	23.94	0.05
p40	26.32	0.06
p50	28.67	0.06
p60	31.15	0.06
p70	34.00	0.07
p80	37.62	0.08
p90	43.29	0.12
p92	45.03	0.14
p94	47.23	0.16
p95	48.61	0.17
p96	50.27	0.20
p97.5	53.70	0.25
p98	55.28	0.26
p99	60.12	0.39
p99.5	64.77	0.52
p99.9	74.84	1.10

Fig. 9. EU15 toothpaste exposure (g/day) for consumers only (males and females).

- Giving study participants unfamiliar products to use for the purpose of the study, is known to alter their habitual product usage (TNS, personal communication).
- Cosmetic product consumers often use more than one product of the same type (for example, products stored in gym bags, used in the place of work or in hotels). TNS data indicates that by supplying the same product to all subjects in a study the investigator may miss up to 10% of use occasions of toothpaste and up to 20% use occasions of shampoo. In addition, the quantity of a cosmetic product used by a consumer is related to brand

specificities, such as product's viscosity, perfume etc. This information is lost in the artificial scenario when all study subjects are using the same product.

- *Data analysis method:* The not-unexpected outcome of this study was a clear demonstration of the variability of frequency and amount of product used per event, in the population of cosmetic product users. A new statistical population modeling was required to capture this complexity of habits and practices.
  The modeling of exposure estimates to consumer products across the European population is a complex task, which necessitates extrapolation from separate data sources (in this case three databases) to obtain a data set that contains frequency of use and amount of the product used per event, for each product and for each country.
  In this analysis probabilistic methods were used, which are standard in food exposure assessment (Gibney and Van der Voet, 2003; McNamara et al., 2003) and in wider areas of risk assessment (e.g., http://saphire.inl.gov). The novelty of the approach in this study is that all the raw data were used in the model calculation. This approach requires large computing power to handle the data and to perform the analysis. The results of the calculations are closer to reality because the detail in the raw data is not lost in being summarised by a parametric distribution in the model input. Consequently the model is kept as close to reality as possible.
  The advantage of using the raw data-driven method is that it allows the software to assign an amount of product used at each product usage event, drawn from the actual usage behaviour in the ISC study. This means that only plausible amount values are chosen for each product usage event. Finally the amount used was randomly assigned from the available data distribution based on the gender, age group and in the cases where correlations were important, based on the frequency of use of the product for that individual.
- *Inclusion of the bodyweight data:* Recent body weight distributions for each of the studied populations were obtained from the ECETOC Exposure Factors Sourcebook (ECETOC, 2001; Eurostat, 2002). In addition, body weights and heights of the volunteers taking part in the ISC usage test, were also recorded. The ISC parameters fitted well within the European published data.

4.2. Analysis of the results

The results of this study in terms of daily exposure (g/day) to the studied cosmetic products are not dissimilar to the currently used exposure parameters (SCCP, 2006) which are based on cosmetic companies' in-house product use data compiled by the manufacturers more than 15 years ago. However, the new results have demonstrated that the current values, hitherto considered "typical" or "average", represent in fact the high end (90th percentile) of a conservative exposure model. It is worth noting that the value for Deodorant/AP non-spray has increased, from 0.5 g/day (SCCP, 2006) to 1.5 g/day (90th centile), probably reflecting the changing habits in personal hygiene in the last 15 years.

The use of raw data for the analysis resulted in distribution histograms of different and characteristic shape for each product type, suggesting that in real life different product types are associated with their individual use pattern in the population.

The important new finding of this study, the inverse correlations found between the frequency of use and amount used per event for the body lotion, shampoo, facial moisturiser and toothpaste, but not for the lipstick and the underarm products, further support the notion of the individuality of use pattern of different cosmetic products. The most important consequence of the correlation finding is that it is not appropriate to calculate daily exposure by simple multiplication of the maximum frequency per day value by the maximum amount per use value for those products for which the correlation exists.

In the case of the body lotion in this study, such worst-case scenario calculation would have resulted in the unrealistic exposure value of 47 g/day, well above the calculated 99.9th percentile of 17 g.

4.3. Uncertainties of the outputs

It is important in the probabilistic analysis to distinguish between uncertainty due to a poor characterisation of the studied phenomenon, which may be reduced through further studies, from the uncertainty due to a true heterogeneity of the studied population, which is usually irreducible.

In the present study, the uncertainty of the latter type is reflected in the distribution of result values: thus a given percentile reflects the fraction of the population considered and should be interpreted as "*there is 95% probability* (*level of confidence*) *that at most y% of the population will exceed* × *grams of daily product use*".

4.4. Risk assessment based on the study results

Cosmetics are the source of daily, population-wide and often long-term exposure to a variety of substances. Their safety relies on the toxicologist's ability to set correct concentration limits for individual ingredients. Essential to this task is the knowledge of exposure to cosmetic products in the marketplace: although the ingredients' concentrations are under manufacturer's control, it is the consumer who decides how often the product is used and what amount is used at each occasion. Consumers' habits may change with time and this study provides new data for the use in the risk assessment of cosmetic ingredients.

The most important aspect of exposure assessment is not to underestimate the exposure of the population to the products of interest. For this reason there were a

number of conservative factors built into this analysis to ensure that this was the case: all products recorded by the Europanel as purchased, were assumed to have been used and at every stage of the simulation the largest scale factor was used. The constructed European Population Model contained 30,000 individuals, all of whom used each of the products as the highest consuming nation studied individually. An important advantage and practical application of the probabilistic approach to exposure is that it permits to estimate the fraction of the population concerned by the particular exposure level, thus aiding the decision making process in the risk assessment for a given substance

The design of this study could serve as a model for conducting assessments of population exposures to chemicals in products other than cosmetics.

Conflict of interest statement

There are no conflicts of interest.

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