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and Food of Denmark**
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Survey of triclosan in cosmetic products

Survey of chemical
substances in consum-
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Sources must be acknowledged.

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Preface

The project is part of the chemicals initiative, focusing on consumers' exposure to hazardous chemicals. The purpose of the study is:

- to provide an overview of the actual occurrence of triclosan in cosmetic consumer products on the Danish market, as well as products in which triclosan occurs,
- to assess whether there has been any change in triclosan consumption since the previous survey from 2006,
- to estimate the amounts of triclosan used in cosmetic products in Denmark and the EU, and
- to examine the proportion of triclosan used in cosmetic products on the European market that comes from manufacturers in the EU.

The project was carried out from March to June 2016 by COWI. The project was overseen by a steering committee with the following members:

- Jette Rud Heltved, Danish Environmental Protection Agency
- Dorte Bjerregaard Lerche, Danish Environmental Protection Agency
- Elisabeth Paludan, Danish Environmental Protection Agency
- Carsten Lassen, COWI
- Marlies Warming, COWI.

Summary and conclusion

This project includes a survey and a mass flow analysis of triclosan in cosmetic products.

Survey

The survey data was collected via literature search, data retrieval from Danish (The Danish Consumer Council TÆNK) and German (Codecheck) consumer product databases, as well as from a shop survey of cosmetic products in six Danish retailers. The purpose of the survey was to identify which product groups contain triclosan, as well as to estimate the proportion of triclosan-containing products as compared to products that do not contain triclosan.

The use of triclosan, according to the Cosmetics Regulation, is limited to toothpaste, hand soap, body soap/shower gel, face powder and blemish concealer, nail products for cleaning the fingernails and toenails before the application of artificial nail systems, deodorant (non-spray) at a concentration of up to 0.3%, as well as to mouthwash at a concentration of up to 0.2%. The survey therefore includes these eight product categories in which the use of triclosan is permitted.

The assessments from the consumer product databases and the shop survey indicate that triclosan is most frequently found in toothpaste, deodorant, nail products and hand soap. The proportion (%) of products containing triclosan in the assessments can be seen in Table 1. The assessment results are of the same magnitude. Furthermore, a good accordance between the triclosan-containing products identified in the TÆNK database and shop survey has been found.

TABLE 1
COMPARISON OF THE PROPORTION OF TRICLOSAN-CONTAINING PRODUCTS COMPARED TO THE TOTAL NUMBER OF REGISTERED PRODUCTS IN THE ASSESSMENTS

Product category	TÆNK ¹ (number of products)	TÆNK ¹ (number of scans)	Codecheck ¹ (number of products)	Shop survey
Toothpastes	0,68%	3,2%	3,4%	1,3%
Nail product	-	-	-	25 %
Deodorants	3,4%	0,77%	2,2%	5,2%
Hand soap	0,60%	0,21%	0,4%	0%
Body soap/shower gel	0%	0%	0,1%	0%
Face powders	0%	0%	0,2%	0%
Blemish concealers	0%	0%	-	0%
Mouthwashes	0%	0%	0,5%	0%

¹ Consumer product database.

For the product groups of body soap, face powder, blemish concealer and mouthwash, no products containing triclosan are identified either in the shop survey or in the Danish database. In the German database, triclosan is found in body soap, face powder and mouthwash, but since product registrations in the German database may be outdated, emphasis is put on the results from TÆNK and the shop survey. Therefore, the focus of the mass flow analysis is on the following four product categories: toothpaste, deodorant, nail products and hand soap. In the mass flow analysis, the lowest and the highest frequencies, respectively, found for each product group are used.

Mass Flow Analysis

The main field of application of triclosan is in cosmetics and personal care, which according to a new international market assessment constitutes approximately 68% of the global use of triclosan. Other uses include paints (8%), disinfection and medical use (16%) and uses in plastic materials, toys and appliances (8%). The distribution is not stated specifically for the EU, where the situation may be different.

The majority of the production and consumption of triclosan occurs in Asia, where there is a total production of approximately 3,200 tonnes per annum, while the production in the EU was 850 tons in 2015, according to a market analysis. The only European registrant has registered a production of 100 to 1000 tonnes¹ (2015). In relation to population numbers, triclosan consumption in Asia and other parts of the world is less than in Europe. Data from the market survey does not give occasion to assume that triclosan is more frequently used in products imported from outside the EU. However, it cannot be excluded that for some product types the frequency may be higher for products manufactured outside the EU. Similar to the situation in Europe, global production and consumption has been decreasing over the last 5 years. The majority of the triclosan produced in the EU is also used for production in the EU. According to the market survey, only modest import from countries outside the EU occurs.

There is no production of triclosan in Denmark. According to the Association of Danish Cosmetics, Toiletries, Soap and Detergent Industries (SPT), there are also no companies that use triclosan in the production of cosmetic products in Denmark, and thus, there is no import of triclosan as a chemical substance for the production of cosmetics in Denmark.

For the four relevant product groups, import and export volumes are extracted from the Danish and European trade statistics. The majority of cosmetic products consumed in the EU are also produced in the EU and only a small portion is imported from countries outside the EU. Similarly, Denmark imports and exports far more cosmetic products within the EU than outside the EU.

Based on data on the trade and production of cosmetic products, the consumption of triclosan is estimated to be 3.8 to 37.4 tonnes in the EU and 0.2 to 0.9 tonnes in Denmark. The majority of the amount of triclosan in Denmark comes from the import of cosmetic products from other EU countries. It is noted, however, that there are a number of uncertainties related to the calculation, possibly leading to an over- or underestimation of the amount of triclosan in products in Denmark or the EU. A former survey on triclosan from 2006 indicated a consumption of triclosan of 3.9 and 1.8 tonnes triclosan in 2000 and 2004, respectively, in products for both professional and consumer uses in Denmark.

The main difference between the use of triclosan in the EU, as indicated in the market survey (841 tonnes for 2015), and the calculated amount in cosmetic products on the market based on trade statistics (from 3.8 to 37.4 tonnes) may occur because the majority of triclosan is used for purposes

¹ The Registrant has in 2016 updated his registration dossier on the production of triclosan into 10 – 100 tonnes per year.

other than cosmetics. From the description of the marketed applications of triclosan, uses may include medical applications, for example, or use as a biocide. Triclosan may also be used in products for the professional market, which were not included in the survey. These possibilities, as well as a number of uncertainties in the calculation, are discussed in the report in relation to the mass balance. It is expected that the market survey provides a fairly accurate picture of the production of and the market for triclosan, but it cannot be excluded that the survey to some extent overestimates the consumption and production in the EU.

1. Introduction

The project is part of the chemicals initiative, focusing on consumers' exposure to hazardous chemicals. Triclosan is a substance that is toxic to bacteria and fish and other aquatic organisms. Furthermore, the substance is suspected to develop resistance in bacteria and to be endocrine disrupting. The European review for endocrine characteristics is however still pending (Danish EPA, 2016).

The use of triclosan has been banned for some applications, but the substance is approved as a preservative in selected cosmetic products. It is used in products such as toothpaste, hand soap, body soap/shower gels face powder and blemish concealer, nail products for cleaning fingernails and toenails before the application of artificial nail systems, and deodorant (non-spray deodorants) at a concentration of up to 0.3%, and in mouthwash at a concentration of up to 0.2%.

When nail products are mentioned in the report, nail products for cleaning fingernails and toenails before the application of artificial nail systems are therefore meant, unless otherwise stated.

Triclosan does therefore still occur in cosmetic products for consumers and as an industry chemical. It is therefore important to assess triclosan for potential hazardous effects. Denmark currently cooperates together with The Netherlands on behalf of the EU to further examine the substance (substance evaluation under REACH). This survey and mass flow analysis provides an overview of regulation, occurrence and trade as regards triclosan.

Chapter 2 contains a description of the method for the survey and mass flow analysis. Chapter 3 describes the legislation governing triclosan, while the subsequent chapters (4 and 5) provide the results of the survey and mass flow analysis.

1.1 Objective

This project comprises a survey of triclosan and a mass flow analysis of the substance. The objective of the survey is

- to provide an overview of the actual occurrence of triclosan in cosmetic consumer products on the Danish market, as well as products in which triclosan occurs, and
- to assess whether there has been any change in triclosan consumption since the previous survey (2006).

The purpose of the mass flow analysis is:

- to estimate the amounts of triclosan used in cosmetic products in Denmark and the EU
- to examine the proportion of triclosan used in cosmetic products in the European market that comes from manufacturers in the EU.

1.2 Delimitation

Triclosan may be used in other products than cosmetic products, e.g. biocidal products, biocide-treated articles, detergents, toys, medical devices and pharmaceuticals, as referred to in chapter 3 about the regulation of triclosan. No survey on triclosan has been performed on these applications, as it is presumed that the major use is in cosmetic products. In the mass flow analysis, data on other applications than in cosmetic products are given in case of such data have been identified.

Based on the cosmetics regulation, triclosan is restricted for use in toothpaste, hand soap, body soap/ shower gel, face powder and blemish concealer, nail products for cleaning the fingernails and toenails before the application of artificial nail systems and deodorant (non-spray) at a concentration of up to 0.3 %, as well as in mouthwash at a concentration of up to 0.2%. Therefore, triclosan is no longer permitted in many leave-on products such as creams and body lotions.

This survey will therefore focus on the following eight cosmetic product types:

- Toothpaste
- Hand soap
- Body soaps/Shower gel
- Face powder
- Blemish concealer
- Nail products for cleaning the fingernails and toenails before the application of artificial nail systems
- Deodorant (non-spray)
- Mouthwash.

2. Method

2.1 Method for the survey

Regulation of triclosan

Individual authorities have been contacted to obtain information on relevant legislation in relation to the use of triclosan in cosmetics and other products. A summary of this review is presented in Chapter 3.

Literature search

An internet search for studies documenting the use of triclosan in cosmetic products has been carried out. The search included a targeted search on previous consumer projects and surveys on the website of the Danish EPA, an open Google search for studies from the EU and North America, and a more specific search for publications from the Nordic countries and Germany, assuming that the use pattern of triclosan in these countries is similar to what has happened in Denmark. Publications from before 2006 are not included in this survey because the purpose of this project is to describe development and changes in triclosan occurrence since the previous triclosan survey from 2006 (Borling et al., 2006).

Consumer product databases

Information was collected from two consumer product databases:

The Danish organization The Danish Consumer Council TÆNK Chemistry² launched the app "Kemiluppen" ("Chemistry Magnifier") in December 2015 with which consumers can scan the barcode of cosmetic products with their smartphone. The product is subsequently assessed by the Consumer Council based on its ingredients, resulting in a green, yellow or red colour as a recommendation to consumers.

Codecheck³ is an online database that works the same way as Kemiluppen, but covers the German-speaking countries (Switzerland, Germany, and Austria). The database also includes products other than cosmetics.

Both organizations were contacted in order to request data extraction on the number of registered products containing and not containing triclosan for the survey-relevant product categories, as well as registration dates and number of scans for each product.

Shop survey

In consultation with the Danish EPA, six retailers were selected for the shop survey. The criteria for the selection of shops was that they should cover a broad spectrum of cosmetic products in terms of price and brands and that they could be considered to cover the majority of the Danish market.

COOP has phased out products containing triclosan and was therefore not included in the survey.

² <http://kemi.taenk.dk/bliv-groennere/kemiluppen-tjek-din-personlige-pleje-uoensket-kemi>

³ www.codecheck.info

Triclosan is not allowed in cosmetic products with the Nordic swan ecolabel or in rinse-off products with the EU Ecolabel. To get a true picture of the market, these products were still included in the registration when they were identified in the stores.

Retailers were contacted in advance to make arrangements concerning the shop survey. During the shop visits, all products from each of the eight product categories were registered by taking a picture of the product. Subsequently, the information on all registered products was collected in an Excel sheet for further data processing.

The following stores are included in the study:

- Matas
- Føtex (Dansk Supermarked)
- Rema1000
- Aldi
- Magasin
- Apoteket.

Since no products for cleaning nails before application of artificial nails were identified in the abovementioned stores, the following Danish Internet retailers who sell products for both consumer and professional use were also contacted:

- Nail4you (Internet retailer)
- Chekos (Internet retailer)
- B4Beauty (Internet retailer)
- Neppersnails (Internet retailer).

Additionally, nine beauty salons in Aarhus performing application of artificial nails were visited. It is assumed that the number of nails products identified from Internet retailers and beauty salons is approximately representative of the consumption of these products in Denmark.

2.2 Method for the mass flow analysis

The mass flow analysis aims to illustrate the production and trade of triclosan and triclosan-containing cosmetic products in Denmark and the EU.

The mass flow analysis is based on a framework illustrated in Figure 1 below. The mass flow analysis aims to map the production of triclosan, the use of triclosan in the production of cosmetic products and the occurrence of triclosan in products on the market in non-EU countries, in the EU and in Denmark, respectively. The arrows in the figure hence represent trade in triclosan as a commodity and trade in cosmetics potentially containing triclosan. The analysis is limited to estimating the prevalence of triclosan in products and does not include an assessment of how much triclosan is discharged to the environment.

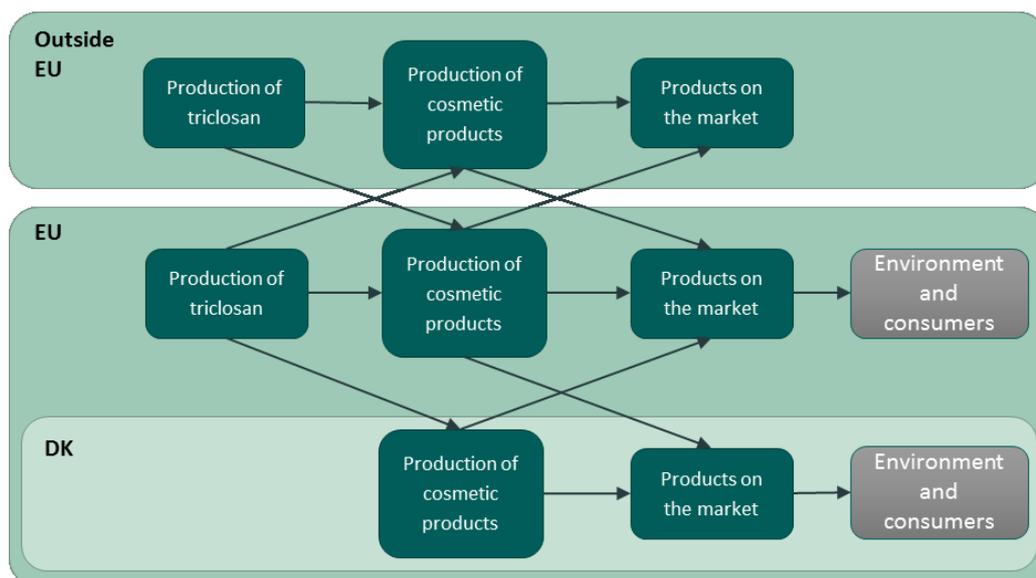


FIGURE 1
OVERVIEW OF THE MASS FLOW OF TRICLOSAN RELATED TO ITS USE IN COSMETIC PRODUCTS

Data on triclosan

There is no specific commodity code for triclosan in the trade or production statistics (Statistics Denmark, Eurostat or the Comtrade database). Thus, production and trade of triclosan cannot be illustrated using statistical data.

Therefore, the public registration data for triclosan from BASF, which at present is the only registrant of triclosan in the EU, was found in the open database of registered substances at the European Chemicals Agency (ECHA 2016) and the trade associations SPT and Cosmetics Europe (via SPT) were contacted in order to obtain information on trade and consumption of triclosan in the EU and Denmark by product group and region.

After identification of triclosan-containing products, contact was made with a deodorant distributor selling several deodorant brands containing triclosan, a distributor of nail products, and the manufacturer of triclosan-containing toothpaste for information about the use of triclosan in Denmark.

In addition, a market report was acquired containing information on production, consumption and trade of triclosan. The market report (QYR, 2016) was prepared by the Chinese research company QYR Chemical & Material Research Centre, which gathers reports from companies and sells the results to the industry. Thus, the report contains some confidential information and only selected information can be used in the present analysis.

Data on cosmetic products

Data on import, export and production of cosmetic products was obtained from Statistics Denmark (import and export in Denmark) and the Eurostat databases International Trade (EU imports and exports) and PRODCOM (national and EU production) for the product types which, according to the survey, may contain triclosan. Data extraction was performed for the last 5 years (2011 - 2015) in order to obtain a representative and robust picture of the tonnages.

In several cases, one commodity code in the statistics covers a larger grouping of products than would be representative of the actual product in question. In these cases, ranges of market shares (%) that the relevant product is supposed to represent out of the entire commodity group are estimated. These ranges are based on the descriptions of the commodity groups in the trade statistics, statements from industry and expert judgment. An overview of all commodity codes, product holdings and their descriptions can be found in Appendix 1.

Even though commodity codes for the relevant product categories (Appendix 1) are available in the European Prodcom database, the database contains no data on production volumes for nail products, toothpastes, deodorants and hand soaps. Therefore, production volumes for these products cannot be indicated based on either the statistics of Denmark or the EU.

The production volume is therefore calculated from the value of the production of cosmetic products, because the production values are available in the listings for each year on the Prodcom database website. The value of production for the relevant product groups are extracted from the most current listings from 2014 and converted using export values and tonnages from 2014 in the Eurostat database International Trade to arrive at an approximate production tonnage. It is assumed that the value per tonne of exported products corresponds well to the value of production. It cannot be excluded that specific products are produced which are to be exported from the EU and sold at a different price per tonne than products destined for the EU market. Consumption is consequently calculated as the sum of EU external imports (2014) and production (2014) minus EU external exports (2014).

Production in Denmark is calculated similar to EU production based on the Danish figures for export volume, value and production value (2014) from the Eurostat and Prodcom databases.

Setting up a model for calculation of mass balance for triclosan

A model to calculate the mass balance for triclosan has been developed. The developed model combines the following information:

- Volumes of import, export and production of cosmetic products for Denmark, the EU and non-EU countries divided by the individual commodity codes of the product types where triclosan may be used;
- The proportion of the tonnage within each commodity code constituted by products containing triclosan;
- The content of triclosan in products: The concentration is assumed to be 0.2% in mouthwash and 0.3% in all other products, unless other information is available, and
- The market share of products containing triclosan compared to the total amount of products for each product category.

All volumes are listed as ranges and the overall results are therefore also presented as ranges.

As an example, the total EU28 Extra imports (imports from countries outside the EU) of triclosan in toothpaste is calculated as

$$\text{Import}_{\text{tri,dental}} = \text{Import}_{\text{CN}} * \text{Proportion}_{\text{CN,dental}} * \text{Concentration}_{\text{tri,dental}} * \text{Frequency}_{\text{tri,dental}}$$

Where:

$\text{Import}_{\text{tri,dental}}$ is the import of triclosan with toothpaste (in tonnes/year);

$\text{Import}_{\text{CN}}$ is the registered EU Extra import of the commodity group 33061000 (in tonnes/year; commodity group numbers by the Combined Nomenclature (CN - Combined nomenclature));

$\text{Proportion}_{\text{CN,dental}}$ is the proportion of the tonnage under CN 33061000, which is made up of toothpaste (No unit, in percentage);

$\text{Concentration}_{\text{tri,dental}}$ is the concentration of triclosan in toothpaste (No unit, in percentage), and

$\text{Frequency}_{\text{tri,dental}}$ is the frequency of the toothpaste that contains triclosan (No unit, in percentage).

The total EU import and export is calculated by adding up the results of all commodity groups. Similar calculations are performed for European consumption, as well as for Danish consumption and import of triclosan in cosmetic products.

3. Regulation of triclosan

Triclosan is regulated in a variety of applications beyond use in cosmetic products in Danish and EU legislation. The regulation of the various uses is summarized in Table 2 below. It should be noted that overlapping between instruments may occur; for example, there may be applications whereby the cosmetic regulation supersedes the biocidal products regulation.

TABLE 2
REGULATION OF TRICLOSAN IN VARIOUS APPLICATIONS.

Application	Regulation
Biocidal products	<p>Biocidal products are products used to control organisms that are harmful to human or animal health or cause damage to natural or manufactured materials.</p> <p>In the biocidal products regulation, 22 different product types (PT) are recognised, including products for disinfection of skin (human hygiene - e.g. hand rubbing alcohol), disinfectants, wood preservatives, rodenticides and insecticides.</p> <p>The active substance of a biocidal product must be approved, or in some cases be under evaluation in the EU – otherwise the active substance may not be used at all. When the active substance is approved, all biocidal products containing the substance must be approved before entering the market and before application.</p> <p>Triclosan has previously been used as active ingredient in biocides for human hygiene (PT1), disinfectants (PT2), in film preservatives (PT 7) and in fibre, leather, rubber and polymerised materials preservatives (PT9).</p> <p>Triclosan has since been assessed, and the substance has not been authorized for use in any of these product types.</p> <p>Use in other biocidal product types is also not allowed, as no applications for its approval as an active substance have been submitted.</p> <p>The prohibition of sale and use of triclosan-containing products in PT 2, 7 and 9 is already in force. For products in PT 1 the decision not to approve triclosan is dated 27 January 2016. Henceforth Article 89, part 2, subparagraph b applies, indicating a ban on sales from 27 January 2017 and a ban on possession and use from 27 June 2017.</p> <p>(The Biocidal Products Regulation - EU No. 528/2012)</p>
Biocides – treated articles	<p>A treated article is a product which has been treated with or intentionally incorporates a biocidal product, i.e. anti-microbial treated clothing, paint containing preservatives etc.</p> <p>Treated articles should only contain active substances that are approved, or in some cases are under assessment according to the Biocidal Product Regulation.</p>

Application	Regulation
	<p>A treated article must be withdrawn from the market if the active substance used to treat the article is not approved.</p> <p>The treated article should be withdrawn from the market, if the active substance of the treated article is not approved. As a general rule the treated article should be withdrawn within <i>180 days from the date of a decision not to approve an active substance or rejection of an application</i> c.f. Article 94 of the Biocidal Products Regulation. This also concerns treated articles from non-EU countries.</p> <p>Treated articles containing a prohibited triclosan-containing biocidal product for human hygiene and articles treated with triclosan-containing disinfectants, film preservatives etc. must therefore all be withdrawn by now.</p> <p>In some EU countries, triclosan is allowed for the treatment of food contact materials made of plastic etc. if the treated products were on the market before 1 September 2013. The use of triclosan in the treatment of food contact materials in Denmark is not allowed as the substance is not on the list of permitted substances in Executive Order no. 822 of 26 June 2013 on food contact materials.</p> <p>After March 1st 2017 a treated article must only be marketed if it is treated with an active biocidal substance, that is approved or is under evaluation for approval for the type of biocidal product on (or inside) the treated article, c.f. Article 94 of the Biocidal Products Regulation.</p> <p>Triclosan has not been submitted for approval as an active substance for PT4 biocidal products, which among others include food contact materials, or for any of the other biocidal product types, and treated articles with triclosan must therefore be withdrawn from the market on February 28th 2017 at the latest.</p> <p>Biocidal treated articles shall among others display a label stating that they are treated with a biocidal product, the active substances concerned and relevant instructions.</p> <p>(The Biocidal Products Regulation - EU No. 528/2012)</p> <p><u>Examples of use in biocidal-treated articles:</u> Triclosan is used to treat sportswear, underwear, shoes etc. and in some cases it is used in food contact materials such as chopping boards.</p>
Cosmetics	<p>Triclosan may be used in the following cosmetic products: toothpaste, hand soap, body soap/shower gel, face powder and blemish concealer, nail products for cleaning the fingernails and toenails before the application of artificial nail systems and deodorants (non-spray) at concentrations of up to 0.3%, and in mouthwash at a concentration of up to 0.2%.</p> <p>(Cosmetics Regulation – EC No. 1223/2009).</p>
Detergents	<p>Preservative used in detergents must be stated on the label (and/or in the Safety Data Sheet when used occupationally) irrespective of its concentration, using when possible the common nomenclature established under Article 8 of Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the</p>

Application	Regulation
	<p>Member States relating to cosmetic products. If triclosan is used as a preservative in detergents for consumers, it must therefore be stated on the label. Cleaning products containing triclosan may not be marketed as anti-bacterial, as in that case they are covered by the Biocidal Products Regulation and the use of triclosan in disinfectants is prohibited.</p> <p>(Regulation on detergents – EC No. 648/2004).</p>
<p>Toys</p>	<p>The directive on the safety of toys (Directive 2009/48/EC) contains no restrictions on the use of preservatives. However, standards for specific substances or toys exist, setting limits for some preservatives. In the standard for finger paint (DS/EN 71-7:2014) it is stated that a maximum concentration of 0.3% triclosan may be used. According to the standard, the preservatives contained in the finger paints should also be clearly indicated on the product. In DS/EN 71-5:2015, which applies to chemical toys that are not experimental sets, the requirement is generally that use only of preservatives that are allowed for use in food and cosmetics may be made.</p> <p>Following standards for toys is not required; however, if the standards are not followed, a type approval of the toy indicating the toy is safe must be present.</p> <p>Toys are exempted in the Biocidal Products Regulation, and it is therefore allowed to use preservatives in toys, which are not approved as preservatives for products during storage.</p> <p>(Directive on the safety of toys – EC No. 48/2009).</p>
<p>Medical devices</p>	<p>Medical devices must meet the essential requirements contained in Annex I to the Executive Order on medical equipment. According to paragraph 7.5 of Annex I to the Order, the equipment must be designed and constructed so that the risks posed by substances leaking from the equipment are limited to the extent possible. Attention should particularly be paid to substances classified as carcinogenic, mutagenic or toxic to reproduction in accordance with Part 3 of Annex VII of the European Parliament and Council Regulation (EC) No. 1272/2008 of 16 December 2008 on classification, labelling and packaging of substances and mixtures.</p> <p>Triclosan is mentioned on the list of harmonized classification and labelling of dangerous substances in Part 3 of Annex VII of the European Parliament and Council Regulation (EC) No. 1272/2008 of 16 December 2008 on classification, labelling and packaging of substances and mixtures.</p> <p>It should furthermore be noted that the risk of any desired and undesired side effect must constitute an acceptable level relative to the performance of the equipment c.f. Annex I section 6 of the Executive Order on medical devices. Demonstration of compliance with the essential requirements of Annex I shall include a clinical evaluation in accordance with Executive Order Annex X c.f. Annex I, Section 6a.</p> <p>(Executive Order no. 1263 of 15 December 2008).</p>
<p>Pharmaceuticals</p>	<p>Triclosan normally needs to be categorized as an excipient (preservative) when used in pharmaceuticals, unless the activity of triclosan is part of the documented clinical effect of the pharmaceutical. Excipients must meet the Medicines Act §51 and §52 regarding quality as well as the Executive Order on</p>

Application**Regulation**

the quality of pharmaceuticals.

New applications or changes to formulations of pharmaceuticals must be requested from and approved by the Danish Medicines Agency. Should the Medicines Agency receive an application indicating that triclosan is included in the formulation of the pharmaceutical the applicant must fulfil a variety of criteria regarding quality and demonstrate that the substance has no toxic properties. Since there is an emphasis on the toxicity of triclosan, it is assumed to be less likely that a company would apply for approval to use the substance.

According to the Danish Medicines Agency database, no pharmaceuticals containing triclosan are approved.

4. Survey

4.1 Previous studies on triclosan in cosmetics

The Danish EPA has published a number of consumer projects over the last 10 years that contain information on triclosan.

Borling et al. (2006) have previously carried out a survey of triclosan in Denmark. Via internet search and outreach to one store and private homes, triclosan was identified in the following cosmetic products (and detergents): deodorant, toothpaste, make-up, acne cream, perfume, baby wipes, antibacterial hand soap, toilet agents and disinfectant wipes. Out of 20 surveyed perfumes, 11 perfumes contained triclosan (about 50%). No further information on the frequency of occurrence was given.

Using questionnaires, the authors estimated amounts of triclosan in various products. A total of 118 companies were contacted either via the trade association SPT or directly, and 75% of the contacted companies responded to the questionnaire. Out of those companies responding to the questionnaire, 33% were retailers or manufacturers of products containing triclosan. The survey showed that cosmetic products accounted for the largest use of triclosan, with 3.9 and 1.8 tonnes of triclosan used in 2000 and 2004, respectively, in products for both professional and consumer use in Denmark. The study showed that the consumption of the substance was decreasing; the consulted companies also expected that the future use of triclosan would decline. The potential turnover of triclosan for the 25% of the contacted companies who did not respond to the survey was not estimated in the study.

Larsen et al. (2006) conducted a survey on hand soaps with a focus on allergens. The project examined 25 liquid hand soaps from the retail market, as well as 25 hand soaps for professional use based on the products' ingredient lists or safety data sheets. Triclosan was identified in two of the professional soaps, but not in any of the retail products.

Rastogi et al. (2007) studied the fragrances and preservatives in deodorants. A total of 97 deodorants were purchased in retail stores, and included various types (55 spray and 42 deodorant roll-on, cream deodorant and deodorant stick) for both men and women. The most commonly used preservative in deodorants was triclosan (in 15% of products). Triclosan was only found in the expensive deodorant sprays or deodorant stick products. Analysis showed that triclosan was present in concentrations ranging from 0.05 to 0.24% (w/w), which is within the maximum allowable concentration (0.3%) in cosmetic products.

Andersen et al. (2015) investigated preservatives in cosmetics and found triclosan in 2 out of 639 investigated cosmetic products. Out of these 639 products, around 100 products were product types where triclosan may be used. Triclosan was identified in one deodorant and after-shave product by examining the list of ingredients during shop visits supplemented with data collected via the Internet.

In a study of triclosan in cosmetics, the American organization Cosmetic Ingredient Review (CIR, 2010) listed the occurrence of triclosan in numerous cosmetic consumer products based on a register of voluntary reports by the cosmetics industry (Cosmetic Registration Program; VCRP). In

this study triclosan was identified in 1.7% of skin care products (primarily lotions and creams), 1.7% of shaving products, 1.2% of baby products (shampoos, lotions, oils, pillows and creams), and 28% of deodorant products, as well as single occurrences in other cosmetic products such as perfumes, hair products, make-up, eye make-up and sunscreen products (<1%). A total of 34,391 products were registered; triclosan was present in 491 of these (1.4%). The study also indicates that deodorant is the product group in which the use of triclosan is most prevalent.

The available studies therefore indicate that triclosan may be contained in deodorant, toothpaste, make-up, acne cream, perfume, products for babies, antibacterial hand soaps (for professional use), toilet preparations and disinfectant wipes, of which deodorant is the most prominent group.

4.2 Consumer product databases

4.2.1 TÆNK

TÆNK extracted data for the relevant product groups in the period 04.13.2016 - 04.21.2016. Since 2015, consumers have had the opportunity to scan cosmetic products and put them into the database; at the time of data extraction, 5,850 products (as separate barcodes) were available in the database (TÆNK, pers. Comm., 2016). Since Kemiluppen is a popular app, the number of products in and consumer scans from the database is increasing.

Products containing triclosan have been identified within the following product groups: toothpaste, hand soap and deodorant (Table 3). TÆNK has identified 24 deodorants containing triclosan (TÆNK, 2016). Some have been discontinued and in some cases, triclosan has been removed from the product (TÆNK, pers. Comm., 2016). It has not been possible to make separate extractions by type of deodorant (e.g. sprays), and in most cases the deodorant type cannot be identified from the product name. Therefore sprays, roll-ons and deodorant sticks are included in the estimation. Additionally two perfumes, one cleansing “milk” (the product is discontinued at this time) and a deodorant spray containing triclosan have been identified via Kemiluppen.

Deodorant is the group in which most products containing triclosan has been identified (3.4%); however, the number of consumer scans (0.77%) indicate that those brands containing triclosan are less in demand than other (larger) deodorant brands. Deodorant brands containing triclosan are on the high end of the price scale according to the information from a press release from TÆNK (TÆNK, 2016). It should be noted, that the use of triclosan is only allowed in non-spray deodorants.

The market share of products containing triclosan compared to all products in the group is calculated both on the basis of the number of products and on the basis of the number of scans of the individual products. Both estimates are taken as an indication of the product's market share in the calculations involved in the mass flow analysis.

TABLE 3
OVERVIEW OF REGISTERED COSMETIC PRODUCTS FROM THE TÆNK APP 'KEMILUPPEN' (DATA FROM TÆNK, PERS. COMM., 2016)

Product category	Number of products in the product category		Proportion of products containing triclosan (%)	Number of scans in the product category		Proportion of products containing triclosan (%)
	Total	Containing triclosan	% per product	Total	Containing triclosan	% per scan
Toothpaste	146	1	0.68%	77,268	2447	3.2%
Handsoap ¹	166	1	0.60%	40,525	87	0.21%
Bodysoap/ shower gel	264	0	0%	46,845	0	0%
Face powder	55	0	0%	25,614	0	0%
Blemish concealer	16	0	0%	10,582	0	0%
Nail products for cleaning ²	-	-	-	-	-	-
Deodorant ³	538	18	3.4%	215,336	1,648	0.77%
Mouthwash	264	0	0%	7124	-	0%
Total	1,449	20	1.40%	423,294	4,182	0.99%

1 Only liquid hand soap

2 No product in the TÆNK database

3 Also includes spray deodorant

It is not the case, however, that *all* products within a brand either contain triclosan or not. Triclosan was found in a single toothpaste product, but in the same brand there are also 45 varieties that do not contain triclosan. Triclosan has been found in 7 deodorant brands but only about half of the products from these brands contain triclosan (Table 7).

TABLE 4
NUMBER OF PRODUCTS CONTAINING AND NOT CONTAINING TRICLOSAN IN DEODORANT BRANDS SHOWING OCCURENCE OF TRICLOSAN (DATA FROM TÆNK, PERS. COMM., 2016).

Brand	Number of products in the brand	Number of products containing triclosan	Number of products not containing triclosan
Deodorant brand 1	2	2	0
Deodorant brand 2	11	4	7
Deodorant brand 3	12	5	7
Deodorant brand 4	4	3	1
Deodorant brand 5	6	2	4
Deodorant brand 6	1	1	0
Deodorant brand 7	1	1	0
Total	37	18	19

4.2.2 Codecheck AG

The German consumer product database Codecheck extracted data for the relevant product groups in the period 5.2.2016 – 03.05.2016 (Codecheck, pers. Comm., 2016). At that time there were 171,630 cosmetic products (as separate barcodes) in the database (the database also includes other products such as food, household goods, baby products, etc.). The earliest registration dates for products in this survey are from 2008.

It has not been possible to receive an extraction of data that also includes the number of scans of the individual products; furthermore, it has not been possible to extract data for all the specific product categories that are relevant in this project. Hand soap is included in the Codecheck category "Soap," which also includes body and facial soaps. If an application area other than hands was evident from the product name or specification, these products were not included. Face powder and blemish concealer are included in the Codecheck category "Make-up and complexion", which also contains liquid make-up, foundation, and similar make-up products. It has also not been possible to sort the products by their name and specification. Similar to the TÆNKs database, it was not possible to extract data on nail products.

Products containing triclosan were found in all product groups (Table 5) and the largest shares were again found in toothpaste (3.4%) and deodorant (2.2%).

The 76 toothpastes containing triclosan were registered or last modified in the database in the period 12.03.2008 - 11.03.2016, with most registrations occurring in 2009 and 2015 (15 and 20, respectively). Approximately 60 toothpastes containing triclosan are distributed over 5 brands, and for the remaining products no brand is indicated.

Half of the deodorants containing triclosan are distributed over 56 brands, and for the remaining products the brand is not specified. The deodorants were registered in the period 06.06.2008 - 04.20.2016 and the registrations are distributed fairly evenly throughout the years.

The 15 hand soaps containing triclosan were registered in the period 28.05.2008 - 17.04.2016 and, according to the product name, about half of these soaps are assumed to be intended for professional use.

There is no reliable information on whether products registered in the beginning of the period are still on the market; however, this is considered unlikely since the last modification time is fairly long ago (Codecheck, pers. Comm., 2016). The products are identified by their barcode in the database. On the basis of the names of the products, it is considered that barcodes may have changed in some cases while products are, in principle, the same. A product can therefore appear two or more times in the database. Since this circumstance applies for both products containing and not containing triclosan, it will not have significant impact on the calculation of proportions.

TABLE 5
OVERVIEW OF REGISTERED COSMETIC PRODUCTS IN THE CODECHECK DATABASE (DATA FROM CODECHECK, PERS. COMM., 2016)

Product category	Number of products in the product category		Proportion of products containing triclosan (%)
	Total	Containing triclosan	% per product
Toothpaste	2,242	76	3.4%
Handsoap ¹	4,039	15	0.4%
Body soap/shower gel	8,302	5	0.1%
Face powders, blemish concealers and other make-up products ²	9,663	21	0.2%
Nail products for cleaning ³	-	-	-
Deodorant ⁴	5,467	120	2.2%
Mouthwash	738	4	0.5%
Total	30,451	241	0.8%

1 May also contain some body soap

2 Not possible to extract data for the individual product types

3 No products in the Codecheck database

4 Also contains spray deodorant

Because of the way the data is presented in the Codecheck extractions and the significant uncertainty about the products' actual presence on the market, an inventory of the triclosan content in the individual products within a brand has not been compiled as has been done for products registered by TÆNK and in the shop survey.

4.3 Shop survey

In the shop survey 913 products have been registered (the figure is adjusted so that there are no duplicate entries). The number of products for each product category and content of triclosan is shown in Table 6.

Subsequent to the shop survey it was announced that Matas has stopped the use of triclosan in its own brand (Matas Striber; Matas, pers. Comm. and Matas, 2016).

In addition, the Danish Pharmaceutical Association announced that the vast majority of the cosmetic products that a pharmacy sells are purchased through joint procurement chains/communities. The three most used procurement chains/communities have announced that there is no triclosan in cosmetic products in their assortment. Therefore, the Danish Pharmaceutical Association considers it highly unlikely that there are cosmetic products containing triclosan in pharmacies (The Danish Pharmaceutical Association, pers. Comm., 2016).

TABLE 6
OVERVIEW OF REGISTERED COSMETIC PRODUCTS IN THE SHOP SURVEY

Product category	Number of products registered	Number of product containing triclosan	Proportion of products containing triclosan (%)
Toothpaste	77	1	1.3%
Hand soap	94	0	0%
Body soap/shower gel	290	0	0%
Face powder	124	0	0%
Blemish concealer	12	0	0%
Nail products	8	2	25%
Deodorant	288	15	5.2%
Mouthwash	20	0	0%
Total	913	18	2%

In the toothpaste product category a single product containing triclosan was identified, while 15 deodorants containing triclosan were identified corresponding to 7 different brands. These deodorants are among the more expensive products and were not found in discount stores.

Triclosan was found in a single toothpaste, but in the same brand 23 other products not containing triclosan were registered in the shop survey. Triclosan has been found in 7 deodorant brands but only about half of the products from these brands contain triclosan (Table 7). Deodorant brands 1-7 are the same as referred to in section 4.2.1, while brand number 8 was not included in the TÆNK database at the time the data extraction was performed.

The nail products are used to clean, degrease and disinfect the natural nails before use of artificial nails. These products are mainly for professional use and therefore have not been found in the consumer product databases or in the six retail stores as described in section 2.1. Through contact with Internet retailers and visits to 9 beauty salons 8 different products were identified (2 products

were used in several salons; 2 salons did not use any products for cleaning the nails before applying artificial nails), of which 2 products contained triclosan (25%). If the data is not corrected for duplicate registrations of the 2 most widely used products, the corresponding share is 27%.

TABLE 7
NUMBER OF PRODUCTS CONTAINING AND NOT CONTAINING TRICLOSAN FROM THE SHOP SURVEY WITHIN THE DEODORANT BRANDS SHOWING OCCURENCE OF TRICLOSAN

Brand	Number of products in the brand	Number of products containing triclosan	Number of products not containing triclosan
Deodorant brand 1	4	3	1
Deodorant brand 2	11	3	8
Deodorant brand 3	4	3	1
Deodorant brand 4	2	1	1
Deodorant brand 5	5	3	2
Deodorant brand 6	1	1	0
Deodorant brand 8	1	1	0
Total	28	15	13

4.4 Discussion and conclusion of the results from the survey

The studies from consumer product databases and the shop survey show that toothpaste, deodorant, nail products and hand soap are the most prominent product categories in terms of triclosan content. Therefore, calculations for these four product categories are performed in the mass flow analysis. The results from the Codecheck database and literature search show that triclosan may also be present in other products. However, since these products are not found in Denmark (c.f. section 4.2.1 and o), and it is not certain that the triclosan-containing products that were identified are still on the market, these product categories (body soap/shower gel, face powder, blemish concealer, mouthwash) are not included in the mass-flow analysis.

There is very little information on concentrations of triclosan in cosmetic products. Rastogi et al. (2007) demonstrated that triclosan is present in concentrations ranging from 0.05 to 0.24% (w/w) in deodorant; therefore, 0.05% is used as the minimum concentration of triclosan in deodorant in the mass flow analysis. In all other cases 0.3% is used, which is the maximum allowed concentration in cosmetic products.

It should be noted that the data from the shop survey and consumer product database are not directly comparable. In the shop survey products from a wide range of Danish stores, which covered both discount and high-end products and still make up a large share of the market of cosmetic products in Denmark, were included. However, the shop survey did not cover small specialty stores such as health food stores, which often also sell cosmetics. The registrations in the consumer product databases are driven by consumer interest in the products, but do not necessarily reflect that the products are purchased accordingly.

The shop survey provides an overview of products actually found on shelves, while databases may contain products that in reality are discontinued. In contrast, the databases include a larger number of products than what could be registered in the shop survey, which means that the low occurrence

of e.g. hand soap containing triclosan would not have been illustrated on the basis of the shop survey alone.

There is a strong correlation between the triclosan-containing products identified in the TÆNK database and the shop survey. In both the TÆNK database and the shop survey, seven deodorant brands are identified of which six brands were identified in both the TÆNK database and in the shop survey.

For the calculations for the mass flow analysis, the market share of products containing triclosan is required to estimate the triclosan content in cosmetic products on the market. The precise market share of each triclosan-containing product is not known, and the shares based on the number of products or number of scans is therefore used as estimates of product market share.

The proportion of triclosan-containing products compared to all registered products in the various studies is summarized for the four product categories. The results are of the same magnitude; however, the results from the Codecheck database are in most cases higher.

In the mass flow analysis the lowest and the highest estimate, respectively, are used.

The proportions from the shop survey are not adjusted for the stores or the products' market share, since the necessary information to do so is not available. The omission of COOP stores (where triclosan-containing products have been phased out), which have a relatively large market share, leads to an overestimation of the shares of triclosan-containing products in relation to the registered products in the shop survey. However, since the results from the shop survey are not significantly higher than the results from consumer product databases, combined with the lack of knowledge of the COOP market share, the results from the shop survey are used without correction for COOP's market share in the mass flow analysis.

TABLE 8
COMPARISON OF THE PROPORTION OF TRICLOSAN-CONTAINING PRODUCTS IN RELATION TO PRODUCTS REGISTERED IN THE DIFFERENT STUDIES

Product category	TÆNK (number of products)	TÆNK (number of scans)	Codecheck (number of products)	Shop survey
Toothpaste	0.68%	3.2%	3.4%	1.3%
Nail products	- ¹	- ¹	- ¹	25%
Deodorant	3.4%	0.77%	2.2%	5.2%
Hand soap	0.60%	0.21%	0.4%	0%
Body soap/ shower gel	0%	0%	0.1%	0%
Face powder	0%	0%	0.2%	0%
Blemish concealer	0%	0%	-	0%
Mouthwash	0%	0%	0.5%	0%

¹ No nail products registered in the consumer product databases.

5. Mass flow analysis

5.1 Uses, production and consumption of triclosan

5.1.1 Uses

Triclosan is used in both professional and consumer products. According to the triclosan-market report, major applications are in cosmetics and personal care, which in 2015 accounted for 37.6% and 30.6% of the global use, respectively (in total approximately 68%; QYR, 2016). It is not specified exactly how the market report distinguishes between cosmetics and personal care. Personal care could, for instance, include disinfectant soaps used by professionals, but this use could also be covered by "disinfectant or medicinal plants". Other uses include paints (8%), disinfection and medical use (16%), as well as use in plastic materials, toys and other appliances (8%; QYR, 2016). The market report does not contain specific information on the distribution of applications in the EU.

5.1.2 Global production

Triclosan is produced in the EU (Germany) and in a number of non-EU countries (India and China). BASF is at present the only registrant in the EU with a registered production of triclosan within the registration interval of at 100-1000 t⁴, (ECHA, 2016). BASF markets two triclosan product lines: Irgacare® MP and Irgasan® DP 300 in the global market. MP Irgacare® is used in mouthwash and in medical applications (BASF, 2016). Irgasan® DP 300 is marketed for use hand and body soap, products for face wash and -cleansing, deodorant, shaving cream, aftershave and acne preparations (BASF, 2016).

Table 9 shows the production volumes for 2011 and 2015 in the global market (QYR, 2016). For all companies that are included in the market report, production has been declining over the period 2011 to 2015; in 2015, production was around 70-75% of 2011 production. The uncertainty of the figures is estimated to be significantly greater than the data (exact indication with four significant figures) suggest. This issue is not specifically mentioned in the report, but such reports are not usually based on highly accurate data from each company; volumes are rather extracted from inter- and extrapolations of uncertain data for each year.

⁴ At October 2016 the registered tonnage was changed by the Registrant into 10-100 tonnes per year

TABLE 9
GLOBAL PRODUCTION OF TRICLOSAN ACCORDING TO THE TRICLOSAN MARKET REPORT (QYR, 2016)¹

Production country/region	Number of companies	Production 2011, tonne	Production 2015, tonne
Europa	1	1,136	850
India	5	1,651	1,241
China	8	2,787	1,988
Other	Not specified	1,006	681
Total	14 + other	6,581	4,760

1 The figures are not verified by sources other than the specified source.

The above production volumes have not been confirmed by the manufacturer, and it has not been possible to obtain further details on the underlying data on which the figures are based, except that they originate from registrations from companies. It is therefore difficult to assess the accuracy of the figures. The specified production of 850 tonnes in Europe in 2015 is consistent with the fact that total imports and production registered under REACH is in the range of 100-1000 t/year.

5.1.3 Global consumption

The global consumption of triclosan has, similar to production, been declining over the years (Table 10). Consumption in the EU in 2015 is equivalent to 62% of that of 2011, while the corresponding global figure is 72%. The EU consumption of triclosan is approximately 20% of the global triclosan consumption in the years 2011 - 2015.

Assuming that 68% (see section 5.1.1) of 2015 consumption is used in cosmetics and personal care, this equates to 572 tonnes in the EU (68% of 841 tonnes) and 2,666 tonnes outside the EU (68% of 921 + 1638 + 1,361 tonnes).

Compared to the population figures (742 m., 1.25 bn. and 1.36 bn. in Europe, India and China, respectively), consumption of triclosan per capita is not significantly different in the three regions. There is no indication that the products imported from countries outside the EU generally contain more triclosan than products produced in the EU, although it cannot be ruled out that for the individual product groups, there may be significant differences among the frequency of products containing triclosan between the individual regions.

TABLE 10
GLOBAL CONSUMPTION OF TRICLOSAN PER REGION (QYR, 2016)

Region	2011	2012	2013	2014	2015
EU	1,348	1,212	1,077	944	841
India	1,226	1,159	1,098	1,009	921
China	2,188	2,055	1,932	1,782	1,638
Other	1,819	1,717	1,618	1,495	1,361
Total (global)	6,581	6,143	5,725	5,230	4,760

5.1.4 Production, import and export of triclosan in Denmark and EU

No production of triclosan in Denmark occurs. According to industry, there are also no companies in Denmark that use triclosan in the production of cosmetic products; therefore, it is expected that there is no import of triclosan to the country. It cannot be excluded, however, that there are individual companies that are not members of the trade organization in Denmark which use triclosan.

Production, import, export and intended use of triclosan in the EU are outlined in Table 11. The specified production in the EU is slightly higher than the production specified in Table 9. There is no immediate explanation for the discrepancy between the two figures. It appears, however, that imports are much smaller than production in the EU, meaning that triclosan used in the production of cosmetic products in the EU is also produced in the EU.

The assumption that 68% of the triclosan is used in cosmetics and personal care corresponds to an import of 8.2 tonnes and an export of 111 tonnes for cosmetics and personal care in 2015.

TABLE 11
PRODUCTION, IMPORT, EXPORT AND CONSUMPTION OF TRICLOSAN IN THE EU (QYR, 2016).

	2011	2012	2013	2014	2015
Production	1,522	1,400	1,251	1,126	991
Import to EU	19	17	15	14	12
Export from EU	193	205	189	196	163
Consumption ¹	1,348	1,212	1,077	944	841

¹ Calculated by QYR (2016) as the sum of production and import minus the export.

5.2 Cosmetic products containing triclosan

5.2.1 Trade, production and consumption in EU

The analysis of production, import and export was carried out for the four product groups identified as containing triclosan in the survey.

The tonnage for the external import and export of relevant cosmetic products in the EU is listed in Table 12 as the average for the years 2011-2014 and for 2015. The import of manicure or pedicure preparations are similar to exports, but export of toothpaste, deodorant and soap (the latter refers to the category 34013000- "Organic surface-active products and preparations for washing the skin ...") are substantially higher than imports.

TABLE 12
EU-EXTERNAL IMPORT AND EXPORT OF COSMETIC PRODUCTS (EUROSTAT INTERNATIONAL TRADE, 2016)

Code(s) ¹	Product group	Import, t/y		Export, t/y	
		Avg. 2011-2014	2015	Avg. 2011-2014	2015
33043000	Manicure or pedicure preparations	16,005	15,709	11,684	12,092
33061000	Dentifrices	18,069	23,357	69,516	66,185
33072000	Personal deodorants and antiperspirants	11,871	13,148	73,127	76,818
34013000	Organic surface-active products and preparations for washing the skin ...	45,523	60,895	90,511	107,907

1 A full description of the codes from the Combined Nomenclature can be seen in Appendix 1

Table 13 shows the internal trade of cosmetic products in the EU. It is seen that internal trade of cosmetic products in the EU is substantially greater than external trade. For manicure or pedicure preparations, internal trade exceeds foreign trade by a factor of 3-4, while for the remaining commodity groups internal trade exceeds external trade by a factor of 3-24. This indicates that production within the EU is significantly higher than imports from non-EU countries. The total intra-EU imports (the sum of registered imports to all EU countries from other EU countries) should, in principle, equal the total reported intra-EU exports. This is not quite the case, illustrating the uncertainty of statistical data (Table 13).

TABLE 13
EU-INTERNAL IMPORT AND EXPORT OF COSMETIC PRODUCTS (EUROSTAT INTERNATIONAL TRADE, 2016)

Code(s) ¹	Product group	Import, t/y		Export, t/y	
		Avg. 2011-2014	2015	Avg. 2011-2014	2015
33043000	Manicure or pedicure preparations	65,590	44,506	39,492	42,220
33061000	Dentifrices	268,271	276,223	254,885	288,861
33072000	Personal deodorants and antiperspirants	266,104	202,535	189,878	217,704
34013000	Organic surface-active products and preparations for washing the skin ...	521,832	547,209	428,673	496,451

1 A full description of the codes from the Combined Nomenclature are provided in Appendix 1

The production volumes can be found in the Prodcom. For the relevant commodity codes, the database contains information only on the value of production, while the tonnage is not listed. To estimate the tonnage it is assumed that the value per tonne of exported products can be used as an indicator of the value per tonne of produced products. There are no data for 2015 in Prodcom; the analysis is therefore based on data for 2014.

Production volumes (Table 14) exceed EU external exports for all products, confirming that the majority of cosmetic products produced within the EU are also used in the EU. Production volumes are similar to or less than internal trade in the EU. This result could indicate that the products are distributed through several countries, so that imports and exports are recorded several times for the same product, and/or that the consumption within the country of production is relatively small.

TABLE 14
ESTIMATED QUANTITIES OF PRODUCTION AND CONSUMPTION OF COSMETIC PRODUCTS IN EU

Codes ¹	Product group	Production ¹ (t/y)		Consumption ² (t/y)	
		2014		2014	
33043000	Manicure or pedicure preparations	48,496		52,640	
33061000	Dentifrices	158,877		109,963	
33072000	Personal deodorants and antiperspirants	247,044		176,272	
34013000	Organic surface-active products and preparations for washing the skin ...	763,866		714,216	

1 Calculated based on the production value in 2014, see section 2.2 and Appendix 2 for further explanation.

2 Calculated as the sum of EU-external import (2014) and production (2014) minus EU-external export (2014), see section 2.2 and Appendix 2 for further explanation.

5.2.2 Trade, production and consumption in Denmark

Contact with industry in Denmark has indicated that there are no companies in Denmark that use triclosan in the production of cosmetic products in Denmark. The tonnage for import and export of the relevant cosmetic products in Denmark are listed in Table 15 as the average for the years 2011-2014 and for 2015. Import and export of the selected cosmetic products in Denmark are of the same magnitude, but import is usually slightly larger than export.

TABLE 15
DENMARK'S IMPORT AND EXPORT OF COSMETIC PRODUCTS (DANMARKS STATISTIK 2016)

Code(s) ¹	Product group	Import, t/y		Export, t/y	
		Avg. 2011-2014	2015	Avg. 2011-2014	2015
33043000	Manicure or pedicure preparations	810	588	395	618
33061000	Dentifrices	10,215	11,139	7,570	7,640
33072000	Personal deodorants and antiperspirants	2,702	2,569	1,671	1,865
34013000	Organic surface-active products and preparations for washing the skin ...	129,111	171,055	96,275	133,100

1 A full description of the codes from the Combined Nomenclature can be seen in Appendix 1

Table 16 shows the corresponding trade figures for trade with other European countries. When comparing with the figures in Table 15, it is seen that the majority (70-99%) of the toothpaste, deodorant, hand soap and nail products are imported from EU countries to Denmark. Similarly, the

majority (84-92%) of the products are exported to EU countries rather than to countries outside the EU.

TABLE 16
DENMARK'S IMPORT AND EXPORT OF COSMETIC PRODUCTS TO/FROM EU COUNTRIES (DANMARKS STATISTIK 2016)

Code(s) ¹	Product group	Import, t/y		Export, t/y	
		Avg. 2011-2014	2015	Avg. 2011-2014	2015
33043000	Manicure or pedicure preparations	586	410	343	552
33061000	Dentifrices	10,058	11,005	6,520	6,510
33072000	Personal deodorants and antiperspirants	2,682	2,552	1,410	1,567
34013000	Organic surface-active products and preparations for washing the skin ...	121,381	161,053	88,839	117,162

1 A full description of the codes from the Combined Nomenclature can be seen in Appendix 1

2 The commodity code covers a wider range of products than those that are relevant in relation to triclosan in this study. The import, export and production figures are therefore multiplied by the estimated share of the relevant product group vs. the whole commodity code, see Appendix 1.

Table 17 shows the production and consumption of cosmetic products in Denmark. For all product groups, production only accounts for a small fraction of export, which could indicate that the majority of products that are exported, has also been imported into Denmark. It should be noted that import and export volumes are derived from Statistics Denmark, while the production is calculated using figures from the European databases (see section 2.2), which in most cases are smaller than the figures in Statistics Denmark.

TABLE 17
ESTIMATED QUANTITIES OF PRODUCTION AND CONSUMPTION OF COSMETICS IN DENMARK

Codes ¹	Product group	Production ¹ (t/y)	Consumption ² (t/y)
		2014	2014
33043000	Manicure or pedicure preparations	39	338
33061000	Dentifrices	68	4,233
33072000	Personal deodorants and antiperspirants	34	1,184
34013000	Organic surface-active products and preparations for washing the skin ...	5,653	49,720

1 Calculated based on the production value in 2014, see section 2.2 and Appendix 2 for further explanation.

2 Calculated as the sum of EU-external import (2014) and production (2014) minus EU-external export (2014), see section 2.2 and Appendix 2 for further explanation.

5.3 Mass balance for triclosan

The calculation of triclosan volumes in the EU and Denmark are based on the assumptions shown in Table 18 and the figures given in the previous section in Chapter 5.

Commodity codes in the trade statistics cover a larger group of products than those that are relevant in relation to triclosan in the present study. The import, export and production figures are therefore multiplied with the estimated share that the relevant product group is supposed to represent out of the entire commodity group. It has not been possible to obtain any estimates from industry on how big a share the individual product groups constitutes out of the respective commodity groups. The shares are therefore indicated as intervals (Table 18, column 2) based on the commodity group description, statements from industry and expert judgment. For further description of the commodity groups, see Appendix 1.

TABLE 18
QUALIFICATIONS CALCULATION OF MASS BALANCE OF TRICLOSAN

Product category	Proportion of the product category in the commodity groups of the trade statistics ¹		Proportion of products containing triclosan in the product category ²		Concentration of triclosan in the product category ²	
	Min.	Max.	Min.	Max.	Min.	Max.
Nail products	0.1 %	1 %	25 %	27 %	0.3 %	0.3 %
Toothpaste	90 %	99 %	0.68 %	3.4 %	0.3 %	0.3 %
Deodorant (non-spray)	50 %	80 %	0.77 %	5.2 %	0.05 %	0.3 %
Hand soap	30 %	70 %	0.21 %	0.6 %	0.3 %	0.3 %

1 See Appendix 1 and text for further explanation.

2 See section 2.2 for further explanation.

Table 19 and Table 20 show the import, export and consumption of triclosan with the cosmetic products deodorant, nail products, toothpaste and hand soap for EU and Denmark, respectively. Based on the trade and production of cosmetic products, the consumption of triclosan is estimated to be 3.8 – 37.4 tonnes in the EU and 0.18 – 0.86 tonnes in Denmark.

Import and export of triclosan in cosmetic products in the EU are likewise calculated based on the proportion of triclosan-containing products identified in the survey, which primarily applies to the Danish (and German) market. Imports of triclosan in products may be higher if the proportion of triclosan-containing products in imports is higher. It is also possible that there are countries in the EU where the proportion of products containing triclosan is greater than in Denmark.

The majority of the occurrence of triclosan in Denmark comes from the import of cosmetic products from other EU countries. Based on figures from 2014, the total import of triclosan to Denmark is 0.54 - 2.6 tonnes (the sum of import from the EU and countries outside the EU), which is of the same magnitude as the calculated consumption. The consumption of triclosan as a component of toothpaste is set to 86.2 kg. This amount is based on information from the manufacturer and is considered to be more reliable than the estimated range. The corresponding estimated consumption is in the range of 78 to 430 kg, and substantiates that the consumption indicated by the manufacturer is within, but at the low end, of the range.

TABLE 19
IMPORT, EXPORT AND CONSUMPTION OF TRICLOSAN IN COSMETIC PRODUCTS IN 2014 IN EU IN TONNES

Product category	Import to EU		Export from EU		Consumption in EU	
	Min.	Max.	Min.	Max.	Min.	Max.
Deodorant (non-spray)	0.03	1.62	0.16	10.5	0.34	22.0
Nail products	0.01	0.14	0.01	0.10	0.04	0.43
Toothpaste	0.42	2.3	1.3	7.2	2.02	11
Hand soap	0.10	0.28	0.19	0.55	1.35	3.86
Total (rounded)	0.66	4.3	1.7	18.0	3.8	37.4

TABLE 20
IMPORT AND EXPORT OF TRICLOSAN IN COSMETIC PRODUCTS IN 2014 IN DENMARK IN TONNES

Product category	Import to DK from EU		Import from countries outside EU ¹		Consumption in DK	
	Min.	Max.	Min.	Max.	Min.	Max.
Deodorant (non-spray)	0.007	0.42	<0.001	0.005	0.002	0.15
Nail products	0.001	0.006	<0.001	0.002	<0.001	0.003
Toothpaste	0.21	1.2	0.002	0.010	0.086 ²	
Hand soap	0.29	0.84	0.017	0.048	0.094	0.63
Total (rounded)	0.52	2.5	0.019	0.065	0.18	0.86

1 Calculated as the difference between the total triclosan import in cosmetic products minus the triclosan import in cosmetic products from the EU.

2 The calculated range is 0.078 – 0.43 tonne. The stated figure (0.086 tonnes) is based on information from the manufacturer and is considered more reliable. This figure is therefore used in the calculation of the total consumption.

The calculated content of triclosan in products sold in Denmark represents about 3% of the corresponding European consumption. This is – taking the Danish and European population figures into consideration – high, as one would normally expect that Denmark's share would be approximately 1% of European volumes.

5.3.1 Discussion of the mass balance

The triclosan-survey from 2006 showed consumption of triclosan in Denmark of 3.9 and 1.8 tonnes triclosan in 2000 and 2004, respectively, in products for both professional and consumer use (Borling et al., 2006). Out of the 1.8 tonnes in 2004, 1.3 tonnes were used in the retail market. The results from this study are significantly lower than the results of the previous survey, but only include consumer products. Borling et al. (2006) used a method of approach (see section 4.1) other

than that used in the present survey; in that study, the triclosan volumes were summed based on information from contacted companies (response rate 75%). The results could therefore be presented as precise numbers instead of ranges. However, it must be assumed that the figures represent an order of magnitude rather than a precise amount, as companies that did not respond to the questionnaire were not taken into account. In addition, there is no information on the possibility that some products could be registered twice in the inventory, in the sense that both retailers and manufacturers of cosmetic products have been questioned. Despite the uncertainties in the figures in the survey from 2006 and the present survey, the results still indicate that there has been a decline in the overall levels of triclosan in cosmetics for consumer use since 2004.

As mentioned in section 0, there is a large discrepancy between the consumption of triclosan for production in the EU (about 841 tonnes according to QYR, 2016) and the estimated total content in cosmetic products sold in 2015 (from 3.8 to 37.4 tonnes in the EU). One possible explanation for the difference may be that the production volumes from the market report (QYR, 2016) are set too high and that the actual production is closer to 100 tonnes than 1000 tonnes. Market reports usually reflect market realities fairly accurately, however; a possible explanation may be that the majority of consumption is for purposes other than cosmetics. Based on the description of marketed products, these could include biocides (including disinfectants) and medical applications. The market report indicates that more than half of the global consumption is used for cosmetics and personal care, but does not provide figures specifically for the European Union. There are likely products that, according to legislation, are not cosmetic products but still are assigned the use category "Cosmetics and personal care" in the market report. Triclosan is permitted as a preservative in detergents and cleaners, and can additionally be used until mid-2017 as an active substance in biocides for human hygiene (PT1).

5.3.2 Uncertainties in the mass balance

The exact market share of the individual triclosan-containing products identified in the survey is not known. Market shares, based on the number of products or number of scans are therefore used as estimates of the products' market shares. Since some products are purchased more often than others, the percentage based on the number of products is not necessarily an accurate picture of the market share. Similarly the percentage based on the number of scans of a particular product in the TÆNK database only reflect the consumers' interest in the product, but does not imply that the product is actually purchased. The highest and lowest estimates are used in the mass balance to achieve the best fit of the product market share.

The calculation of triclosan content in cosmetic products is based on the production of cosmetic products in the EU, which is estimated based on a conversion factor of production value to the production tonnage. This calculation thus also includes an uncertainty that can lead to under- or overestimation of the amount of production and thus the amount of triclosan in products on the market.

The difference between the internal import and export in the EU, as well as differences between Danish imports registered in Statistics Denmark and Eurostat (the latter data is not shown in the report) show that there are significant uncertainties associated with records in the trade statistics. Tonnages for Danish trade are generally noted as lower in Eurostat compared to Statistics Denmark.

The products are listed in tonnages with weight units (tonnes or kg) in the trade statistics. Boxing and weight of packaging are not taken into account in the registrations in the statistics. For many cosmetic products, packaging constitutes a significant part of the total weight. A calculation of triclosan content based on the total weight of the product would therefore result in an overestimation of the triclosan content in the products.

The content of triclosan in products is assumed to be 0.3% in toothpaste, hand soap and nail products since the exact content in the products is not known. Previous analysis has shown that triclosan is present in concentrations between 0.05 to 0.24% (w/w) in deodorant (Rastogi et al. 2007); therefore, 0.05% was used as the minimum concentration and 0.3% as maximum concentration in deodorant. The calculated levels for nail products, hand soap and toothpaste may therefore very well be overestimated by a factor of ca. 2.

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Appendix 1 Commodity codes for cosmetic products

Relevant commodity codes from The Combined Nomenclature 2016

Product type	Commodity code (CN code)	Description of the commodity group	Comment
Toothpaste	33061000	Dentifrices, incl. those used by dental practitioners	It is assumed that toothpaste constitutes 90-99% of the category.
Hand soap	34013000	Organic surface-active products and preparations for washing the skin, in the form of liquid or cream and put up for retail sale, whether or not containing soap	The commodity group includes all soaps for washing the skin. It is believed that hand soap constitutes 30 - 70% of the category.
	34011100	Soap and organic surface-active products and preparations, in the form of bars, cakes, moulded pieces or shapes, and paper, wadding, felt and nonwovens, impregnated, coated or covered with soap or detergent, for toilet use (including medicated products)	According to information from the industry, triclosan is used in liquid hand soap. This group mainly includes soap in solid form, thus it is not considered to be relevant in terms of triclosan content.
Body soap/shower gel	34013000	Organic surface-active products and preparations for washing the skin, in the form of liquid or cream, and put up for retail sale, whether or not containing soap.	Not relevant according to the survey results.
Face powders	33049100	Make-up or skin care powders, incl. baby powders, whether or not compressed (excl. medicaments)	Not relevant according to the survey results.
Blemish concealers	33049900	Beauty or make-up preparations and preparations for the care of the skin (other than medicaments), incl. sunscreen or suntan preparations (excl. medicaments, lip and eye make-up preparations, manicure or pedicure preparations and powders, whether or not compressed)	Not relevant according to the survey results.
Nail products for cleaning the fingernails and toenails before the application of artificial nail systems	33043000	Manicure or pedicure preparations	This group includes all products for manicure and pedicure, including nail polish and nail polish remover. It is assumed that nail agents for cleaning of fingernails and toenails constitutes 0.1 - 1% of the category.
Deodorant (non-sprays)	33072000	Personal deodorants and antiperspirants	There are different views in the industry about how widespread sprays are compared to other deodorant types. It is believed that the non-spray deodorants represent 50 - 80% of the category.
Mouthwash	33069000	Preparations for oral or dental hygiene, incl. denture fixative pastes and powders	Not relevant according to the

		(excl. dentifrices and yarn used to clean between the teeth dental floss)	survey results.
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Relevant codes from the Prodcom database 2014⁵

Product type	Prodcom code (CN code)	Description of the commodity group	Comment
Toothpaste	20421850	Dentifrices (including toothpaste, denture cleaners)	It is assumed that toothpaste constitutes 90-99% of the category.
Hand soap	20421930	Organic surface-active products and preparations for washing the skin; whether or not containing soap, p.r.s.	The commodity group includes all soaps for washing the skin. It is believed that hand soap constitutes 30 - 70% of the category.
Body soap/shower gel	20421930	Organic surface-active products and preparations for washing the skin; whether or not containing soap, p.r.s.	Not relevant according to the survey results.
Face powder	20421400	Powders, whether or not compressed, for cosmetic use (including talcum powder)	Not relevant according to the survey results.
Blemish concealer	20421500	Beauty, make-up and skin care preparations including suntan (excluding medicaments, lip and eye make-up, manicure and pedicure preparations, powders for cosmetic use and talcum powder)	Not relevant according to the survey results.
Nail products for cleaning the fingernails and toenails	20421300	Manicure or pedicure preparations	This group includes all products for manicure and pedicure, including nail polish and nail polish remover. It is assumed that nails agents for cleaning of fingernails and toenails constitute 0.1 - 1% of the category.
Deodorant (non-sprays)	20421960	Personal deodorants and anti-perspirants	There are different views in the industry about how widespread sprays are compared to other deodorant types. It is believed that the non-spray deodorants represent 50 - 80% of the category.
Mouthwash	20421890	Preparations for oral or dental hygiene (including denture fixative pastes; powders and tablets, mouth washes and oral perfumes, dental floss) (excluding dentifrices)	Not relevant according to the survey results.

⁵ <http://ec.europa.eu/eurostat/web/prodcom/data/excel-files-nace-rev.2>

Appendix 2 Data for calculation of production and consumption in EU and Denmark

Exports and production value of cosmetic products in 2014

As described in the methodology section 2.2, the production of the relevant cosmetic products is calculated on the basis of trade and production value of the products. The tables below therefore list exports, value and conversion factors for Europe and Denmark, respectively.

PRODCOM CODE	PRODUCT	Prodcom EU28 Production value 2014 (1000EUR)	Eurostat EU28_INTRA Export Value (EUR)	Eurostat EU28_INTRA Export Quantity (100KG)	Factor EU28_INTRA (EUR/100KG)	EU28 Production (TONNES)
20421300	Manicure or pedicure preparations	592.472	536.725.263	439.332	1.222	48.496
20421850	Dentifrices	674.647	1.277.009.887	3.007.308	425	158.877
20421960	Deodorants and anti-perspirants	1.361.375	1.166.808.753	2.117.363	551	247.044
20421930	Organic surface-active products and preparations for washing the skin ...	1.514.680	926.805.659	4.673.961	198	763.866

PRODCOM CODE	PRODUCT	Prodcom Denmark Production value 2014 (1000EUR)	Eurostat Denmark Export Value (EUR)	Eurostat Denmark Export Quantity (100KG)	Factor Denmark (EUR/100KG)	Denmark Production (TONNES)
20421300	Manicure or pedicure preparations	643	11.091.802	439.332	1.665	39
20421850	Dentifrices	228	38.822.450	3.007.308	336	68
20421960	Deodorants and anti-perspirants	251	27.550.083	2.117.363	733	34
20421930	Organic surface-active products and preparations for washing the skin ...	8855	12.429.473	4.673.961	157	5.653

Import and export in the EU and Denmark in 2014 for calculating consumption

The consumption of cosmetic products in the EU and Denmark are calculated with the respective figures for production, import and export in 2014.

Codes	Product group	Production (tonnes)	Import EU external (100KG)	Export EU external (100KG)	Consumption EU (tonnes)
		2014	2014	2014	2014
33043000	Manicure or pedicure preparations	48496	170.676	129.235	52640
33061000	Dentifrices	158877	227.805	716.946	109963
33072000	Deodorants and anti-perspirants	247044	129.688	837.401	176272
34013000	Organic surface-active products and preparations for washing the skin ...	763866	516.065	1.012.570	714216

Codes	Product group	Production (tonnes)	Import total (kg)	Export total (kg)	Consumption (tonnes)
		2014	2014	2014	2014
33043000	Manicure or pedicure preparations	39	978223	679688	338
33061000	Dentifrices	68	11803121	7638096	4233
33072000	Deodorants and anti-perspirants	34	3433608	2283463	1184
34013000	Organic surface-active products and preparations for washing the skin ...	5653	1.64E+08	1.2E+08	49720

Survey of triclosan in cosmetic products

The report maps out the actual occurrence of triclosan in cosmetic consumer products on the Danish market and shows that triclosan commonly is found in tooth-pastes, deodorants, nail products and hand soaps. Products as body soap/shower gel, face powder, blemish concealer and mouthwash are not found with triclosan. In addition a mass flow analysis is carried out. The mass flow analysis shows that the main field of application of triclosan is in cosmetics and personal care products, and that the majority of the amount of triclosan in Denmark comes from the import of cosmetic products from other EU countries.



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