

Ministry of Environment and Food of Denmark Environmental Protection Agency

Survey of cosmetic products with "probiotic" or "prebiotic" claims

Survey of chemical substances in consumer products No. 171

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Miljøstyrelsen offentliggør rapporter og indlæg vedrørende forsknings- og udviklingsprojekter inden for miljøsektoren, som er finansieret af Miljøstyrelsen. Det skal bemærkes, at en sådan offentliggørelse ikke nødvendigvis betyder, at det pågældende indlæg giver udtryk for Miljøstyrelsens synspunkter. Offentliggørelsen betyder imidlertid, at Miljøstyrelsen finder, at indholdet udgør et væsentligt indlæg i debatten omkring den danske miljøpolitik.

Må citeres med kildeangivelse.

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Summary

The Danish Environmental Protection Agency is experiencing an increasing interest in cosmetic products marketed with the claims "probiotic" and/or "prebiotic".

Objective

The Danish Environmental Protection Agency initiated this consumer project with the aim of providing an overview and obtaining more knowledge about pro- and prebiotic products on the Danish market. The following questions were investigated:

- · What are pro- and prebiotic ingredients and which are used in cosmetic products?
- Which cosmetic product types are found in pro-/prebiotic versions?
- What is the market share of cosmetic products with pro-/prebiotic claims?
- Is there a price difference between pro-/prebiotic products compared to other cosmetic products?
- Is there a difference in durability (shelf life) between pro-/prebiotic products compared to other cosmetic products?
- · Are cosmetic products with pro-/prebiotic claims certified with ecolabels?
- What is the range of pro-/prebiotic raw materials for cosmetics producers?
- How and why are certain cosmetic products claimed as being pro- and/or prebiotic? Are the pro-/prebiotic cosmetic products marketed with special health-related claims?

Method

The questions above were investigated through information gathered from stakeholders, literature searches, and a market survey.

Two Danish industry associations, several Danish and foreign cosmetics manufacturers, the largest Danish cosmetics retailers (Danish Supermarket, COOP, Matas, Magasin, Pharmacies) and other experts in the field were contacted to collect information to answer the above questions.

As part of the market survey, the Chemistry section of the Danish Consumer Council Think provided an extract of their product database, which contains information about a large proportion of cosmetic products that are on the market in Denmark. The extract was made by searching for the names of probiotic bacteria in the ingredient lists. In addition, a retailer survey was carried out to identify cosmetics products with pro-/prebiotic claims from both internet retailers and in a department store.

Results and conclusions

Generally, there is limited available knowledge about ingredients, products and/or an overview of the pro-/prebiotic cosmetics market in Denmark.

Pro- and prebiotic ingredients are well known as dietary supplements and, as a rule, the definitions of the concepts have been developed based on their use as dietary supplements.

The common definition of "probiotic" involves living microorganisms having a beneficial effect on the host, whereby the effect can be documented. Living microorganisms, however, are used only to a limited extent in cosmetic products. Nonetheless, within the cosmetics sector, a number of ingredients that are merely produced by microorganisms are referred to as "probiotic". The most widely used bacterial strain is *Lactobacillus*. *Bifidobacterium* is also often used for production of cosmetics ingredients, whereas ingredients derived from *Lactococcus*, *Streptococcus*, *Leuconostoc*, *Pediococcus* and *Saccharomyces* are listed less frequently on the ingredient lists of certain products.

The common definition of "prebiotic" substances implies that the substances can cause specific changes in the composition and/or in the activity of the host's microflora, that the substances cannot be degraded by the host's own enzymes, that they have a beneficial effect on the health of the host and that the effect can be documented. In cosmetics, the term "prebiotic ingredients" is used in a broader context, i.e. as substances that can be exploited by beneficial bacteria or as substances produced by microorganisms (as mentioned above, these are also often referred to as probiotic ingredients in relation to cosmetics). Alpha-Glucan Oligosaccharide, inulin, lactic acid, and lactobacillus ferment are the ingredients most commonly found in products that claim to be pro-/prebiotic in the retailer survey.

Both communication with the stakeholder (including stakeholder associations, cosmetics manufacturers and retailers) and an internet search show that pro- and prebiotic products are mostly leave-on products, but also include a few rinse-off products. The products identified from the internet retailers' websites are mainly for facial care (69%). In addition, there are a few products for body care (11%), soap and hygiene (11%), and some products for baby care products, hair care and make-up (3% in each category).

According to stakeholder consultation, cosmetic products with pro-/prebiotic claims are still niche products; the market share of these products is below 1% (in turnover). In the examination of the products in a department store (which primarily led specialty and luxury cosmetics, as the relevant products are essentially only found among such products) the number of pro-/prebiotic products accounted for 1.7% of all facial care products. The extract from the product database showed 0.59% of products that contained a bacterially-derived ingredient. The different estimates were on the same order of magnitude and confirm that pro-/prebiotic products constitute a niche segment in cosmetics. At the time of writing, the products were not yet found in discount- and supermarkets, but only in department stores, specialized cosmetics retailers, or pharmacies. A significantly larger selection was available through internet retailers. The data support the stakeholder estimate of a total market share of below 1% for cosmetic products with pro-/prebiotic claims.

A total of 932 products were investigated in the retailer survey, of which 80 unique products were marketed with pro-/prebiotic claims.

Products with pro-/prebiotic claims were similarly priced as other specialty cosmetic products. With regard to durability dates, the results showed that pro-/prebiotic products did not differ from other cosmetic products. About one third of the pro-/prebiotic products were labelled with the ECOcert label. In addition, a few of the products in the department store were labelled with the Nordic Ecolabelling Swan.

The claims of the pro- and prebiotic products identified in the retailer survey were reviewed. The claims "probiotic", "prebiotic" or similar are typically used in: i) the product description printed on the packaging; ii) a display on the Internet retailers' product homepages; or iii) part of the product/brand name that is printed on the packaging. Most claims relate to some general positive health effects on the skin; for example, "creating better balance" or "moisturizing". In addition, some of the pro-/prebiotic products claim to be effective against skin disorders and/or skin problems. However, these claims are also common for other cosmetic products. In contrast, health-related claims concerning changes in the skin's naturally occurring microbial community appear to be used specifically for pro-/prebiotic cosmetics. Overall, a comparison of information obtained from stakeholder consultation, literature/internet searches, the product database and the retailer survey indicates that there is no clear relationship between pro-/prebiotic claims and ingredients in cosmetics.

Sammenfatning

Miljøstyrelsen oplever en stigende interesse for kosmetiske produkter markedsført med anprisningen "probiotisk" og/eller "præbiotisk".

Formål

Miljøstyrelsen har igangsat dette forbrugerprojekt med det formål at danne et overblik og fremskaffe mere viden om pro- og præbiotiske produkter på det danske marked. I den forbindelse undersøges følgende spørgsmål:

- Hvad er pro- og præbiotiske ingredienser og hvilke bruges i kosmetiske produkter?
- Hvilke kosmetiske produkttyper findes i probiotiske/præbiotiske udgaver?
- Hvor stor en markedsandel har pro- og præbiotisk anpriste kosmetiske produkter?
- Er der prismæssig forskel på probiotiske/præbiotiske produkter ift. "konventionelle" produkter?
- Er der forskel i holdbarheden mellem probiotiske/præbiotiske produkter ift. "konventionelle" produkter?
- Er probiotiske produkter certificeret i forhold til nogle af de klassiske mærkningsordninger?
- Hvor stort er udvalget af probiotiske/præbiotiske råvarer for producenterne?
- Hvordan og af hvilken årsag anprises kosmetiske produkter som pro- og/eller præbiotiske? Markedsføres de probiotiske/præbiotiske kosmetiske produkter med særlige sundhedsrelaterede anprisninger?

Metode

De nævnte spørgsmål undersøges dels gennem informationsindhentning fra brancheaktører og litteratursøgning, dels gennem en markedsundersøgelse.

To danske brancheorganisationer, en række danske og udenlandske kosmetikproducenter og større kosmetikforhandlere (Dansk Supermarkedet, COOP, Matas, Magasin, Apotekerne) samt andre videnspersoner er blevet kontaktet for at indsamle informationer til ovenstående spørgsmål.

I markedsundersøgelsen er der foretaget et udtræk af Forbrugerrådet Tænk Kemis database, som indeholder en stor andel af kosmetiske produkter, som er på markedet i Danmark. Udtrækket blev foretaget ved at søge på navne af probiotiske bakterier i ingredienslisterne. Derudover blev der gennemført en butiksundersøgelse som identificerede en række pro-/præbiotisk anpriste produkter både på internetforhandlernes hjemmesider og i en fysisk butik.

Resultater og konklusioner

Generelt er der begrænset tilgængelig viden om ingredienser, produkter og/eller overblik over markedet af pro-/præbiotisk kosmetik i Danmark.

Pro- og præbiotiske ingredienser er velkendt som kosttilskud og definitioner af begreberne er som udgangspunkt udviklet på baggrund af deres anvendelse inden for fødevarer/kosttilskud. Den gængse definition af "probiotisk" indebærer anvendelsen af levende mikroorganismer, som har en gavnlig effekt på værten, samt at effekten kan dokumenteres. Levende mikroorganismer anvendes dog kun i yderst begrænset omfang i kosmetiske produkter. Inden for kosmetik derimod betegnes en række ingredienser, som er produceret vha. mikroorganismer, som "probiotiske". Den mest anvendte bakterieslægt er *Lactobacillus. Bifidobacterium* forekommer også ofte, mens ingredienser afledt af *Lactococcus, Streptococcus, Leuconostoc, Pediococcus* og *Saccharomyces* også er listet på ingredienslisterne af enkelte produkter.

Den gængse definition på "præbiotiske" stoffer indebærer, at stofferne giver specifikke ændringer i sammensætningen og/eller i aktiviteten af værtens mikroflora, at stofferne ikke kan nedbrydes af værtens egne enzymer, at de medfører en gavnlig effekt på værtens sundhed og at effekten kan dokumenteres. Indenfor kosmetik omtales præbiotiske ingredienser noget bredere, dvs. som stoffer, der kan udnyttes af gavnlige bakterier eller som stoffer, der er produceret vha. mikroorganismer (som nævnt ovenfor betegnes disse også ofte som probiotiske ingredienser i forhold til kosmetik). Alpha-Glucan Oligosaccharide, Inulin, Lactic Acid, og Lactobacillus Ferment er de ingredienser, som er hyppigst fundet i pro-/præbiotisk anpriste kosmetiske produkter i butiksundersøgelsen.

Både kommunikation med branchen (bl.a. brancheorganisationer, kosmetikproducenter og forhandlere) og søgning af pro- og præbiotisk anpriste produkter i webshops viser, at de anpriste produkter primært er leave-on produkter, men også omfatter få rinse-off produkter. Produkterne, som er identificeret fra internetforhandlernes hjemmesider, er hovedsageligt til ansigtspleje (69%). Derudover blev der fundet få produkter til kropspleje (11%), sæbe og hygiejne (11%), og enkelte produkter inden for babypleje, hårpleje og kosmetik/make-up (3 % i hver kategori).

Mht. markedsandelene vurderer flere branchekontakter at pro- og præbiotisk anpriste produkter stadig er nicheprodukter og at markedsandelen af disse produkter ligger under 1% i omsætning. I undersøgelsen af produkterne i en fysisk butik (som fører primært special- og luksuriøskosmetik, da de relevante produkter udelukkende markedsføres dér) udgjorde antallet af de pro-/præbiotisk anpriste produkter 1,7% af alle produkter inden for ansigtspleje, mens udtrækket fra Kemiluppens database viste 0,59% produkter, som indeholdt en bakterieafledt ingrediens. De forskellige estimater ligger i samme størrelsesorden og bekræfter, at pro- og præbiotisk anpriste produkter udgør et nichesegment indenfor kosmetik. Produkterne findes (endnu) ikke i dagligvarebutikker (discountmarkeder og supermarkeder), men derimod i stormagasiner, hos specialiserede kosmetikforhandlere, eller på apoteker. Et væsentlig større udvalg er tilgængelig via internetforhandlerne. Alt i alt bekræfter ovenstående branchens formodning om at den samlede markedsandel ligger under 1%.

I alt indgik 932 produkter i butiksundersøgelsen, heraf blev 80 unikke produkter anprist med pro- og/eller præbiotisk.

Prismæssigt ligger pro- og præbiotisk anpriste produkter på niveau med andre specielt udviklede kosmetiske produkter. Mht. til konservering og holdbarhed viser resultaterne, at pro- og præbiotisk anpriste produkter ikke afviger fra anden kosmetik. Ca. en tredjedel af de pro-/præbiotisk anpriste produkter var mærkede med ECOcert mærket. Enkelte produkter, som forhandledes i stormagasinet, var derudover mærket med det nordiske miljømærke Svanen.

Anprisningerne af de i butiksundersøgelsen identificerede pro- og præbiotisk anpriste produkter blev gennemgået. Anprisningen som "probiotisk", "præbiotisk" eller lign. fremgår typisk af: i) produktbeskrivelsen, som er printet på emballagen, ii) vises på forhandlerens produkthjemmeside, eller iii) er en del af produkt-/mærkenavnet, som vises på forsiden af emballagen. De fleste anprisninger relaterer sig til nogle generelle positive sundhedseffekter i huden, f.eks. skabe "bedre balance" eller virke "fugtgivende". Derudover anprises nogle af de pro-/præbiotiske produkter til at kunne afhjælpe hudlidelser og/eller hudproblemer. Disse anprisninger er også almindelige for andre kosmetiske produkter. Det, der tilsyneladende adskiller anprisningen af pro-/præbiotisk kosmetik fra anden kosmetik, er, når der fremhæves effekter, som vedrører ændring af hudens naturligt forekommende bakteriesamfund. Sammenligning af resultater fra branchen, litteraturen/internettet, produktdatabasen og butiksundersøgelsen viser, at der ikke er en entydig sammenhæng mellem anprisninger og ingredienser i kosmetik.

1. Background and objective

1.1 Background

The Danish Environmental Protection Agency is experiencing an increasing interest in cosmetic products marketed with the claim "probiotic" and/or "prebiotic".

Probiotic food products such as fermented milk products and food supplements (probiotics) are used for their beneficial effects on health, e.g. by counteracting diarrhoea (Medical Manual, 2016). Prebiotics are short- or long-chain carbohydrates and known from their use as dietary supplements. Prebiotics have beneficial effects on the intestinal microbiota and therefore on the health of the host (Vignæs, 2012). The concepts "probiotic" and "prebiotic" are discussed in more detail in Chapter 2.

The positive effects of pro- and prebiotics on the intestinal bacterial community may also be applicable to the skin's bacterial community (Forum, 2018; Welt, 2016).

However, it is not clear how effective pro- or prebiotic cosmetic products are, if their effects are consistent with the product's claims, how the products are advertised and how consumers can recognize a pro- or prebiotic cosmetic product. The Danish Environmental Protection Agency initiated this study to illuminate some of these aspects.

1.2 Objective

The purpose of this study was to provide an overview and more knowledge about products that claim to be pro- and prebiotic on the Danish market, including:

- What are pro- and prebiotic ingredients and which are used in cosmetic products?
- Which cosmetic product types are found in pro-/prebiotic versions?
- What is the market share of cosmetic products with pro-/prebiotic claims?
- Is there a price difference between pro-/prebiotic products compared to other cosmetic products?
- Is there a difference in durability between pro-/prebiotic products compared to other cosmetic products?
- · Are cosmetic products with pro-/prebiotic claims certified with ecolabels?
- What is the range of pro-/prebiotic raw materials for cosmetics producers?
- How and why are certain cosmetic products claimed as being pro- and/or prebiotic? Are the pro-/prebiotic cosmetic products marketed with special health-related claims?

1.3 Delimitation

This project was primarily a survey with the above objectives. Thus, the project was not a study of the effects of pro- and/or prebiotically advertised cosmetic products on skin or other organs.

Therefore, the survey does not include an assessment of documentation for any health effects that might form a basis for the claims.

There are also a number of probiotic products that claim beneficial skin effects on the market, intended as dietary supplements. These products were not included in this survey, which focused only on cosmetics applied to the skin.

2. Collection of knowledge about ingredients, product types and the market for cosmetics with pro- and prebiotic claims

The primary purpose of this chapter is to provide an overview of available knowledge from the cosmetics stakeholders, supplemented with information retrieved via literature search.

2.1 Methods

Information was collected by internet search and via communication with stakeholders.

The following stakeholder organizations, companies and other experts in the field were contacted:

- Stakeholder organizations:
 - Cosmetics & Hygiene industry association (formerly SPT)
 - Industry association VKH Washing, cosmetics and household industry
- Cosmetics Manufacturers:
 - DermaP harm A/S, Denmark
 - Allison A/S, Denmark
 - Aurelia Skincare Ltd, United Kingdom
 - Esse Skincare, South Africa
 - Chrisal NV, Belgium
- Possible source suppliers of pre- and probiotics:
 - Chr Hansen Holding A/S
- Cosmetics retailers:
 - Danish Supermarket Group (Netto discount market, Føtex supermarket, Bilka supermarket, Salling department store)
 - COOP (Kvickly supermarket, Super Brugsen supermarket, Dagli 'Brugsen supermarket, Irma supermarket, Fakta discount market)
 - Magasine department store
 - Matas cosmetics retailer
 - Danish Pharmacies Association
- Others:
 - Danish Consumer Council Think Chemicals (Danish consumer organisation)
 - Danish Beauty Award (DBA)
 - Helle Forum, cosmetics journalist and author

The above organisations were asked the questions listed in section 1.2 by the respondents' preferred communication form (telephone, e-mail or interview). Answers were anonymous and companies/organizations are generally referenced as "stakeholders" in this report.

2.2 Results from knowledge collection

Communication with the stakeholders made it clear that the pro-/prebiotic cosmetics are "trendy" and are the subject of great interest among most players. The trend is reflected in the fact that several stakeholders hype pro-/prebiotic cosmetics as a growing market and that these products have won prizes at the Danish Beauty Awards in 2017 and 2018 (Danish Beauty Awards 2017, 2018). The subject has also been a discussion topic at the annual European In-Cosmetics Conference in Amsterdam.¹

Generally, however, there is limited knowledge available about ingredients, products and the market for pro-/prebiotic cosmetics in Denmark.

In the following section ingredients that are typically considered as being probiotic and/or prebiotic, as well as the basis for pro- or prebiotic claims on the products, are examined.

2.2.1 Probiotic ingredients

The general definition of probiotics is "live microorganisms which when administered in adequate amounts confer a health benefit on the host" (Hills et al. 2014). Probiotic products like sour milk products or dietary supplements (probiotics) are used for their beneficial effects on health, e.g. by counteracting diarrhoea (Medical Manual, 2016). The international expert panel on probiotics clarifies that products containing ingredients produced by microorganisms or containing dead microorganisms are not covered by the definition of probiotics (Hills et al., 2014).

According to an article in Dermatology Times (Farris, 2016), which is an online newspaper for a global medical network, probiotic bacteria have proven skin benefits that are related to their properties as fermentation bacteria. The article describes that during fermentation, acidic compounds such as lactic acid are produced. These compounds reduce the pH of the skin and thus counteract the growth of pathogenic bacteria. At the same time, the growth of "beneficial bacteria" is favoured. Some probiotic bacterial strains also produce antimicrobials, organic acids and hydrogen peroxide, which may inhibit pathogens (Farris, 2016).

According to communications with some of the stakeholders, the definitions of pro- and prebiotics in cosmetics is not as defined as it is in food. So far, living bacteria are only used to a limited extent in cosmetic products because their viability, purity and effect are difficult to control in cosmetic products (Dobos, 2017; personal communication with stakeholders, 2018).

A recently published article on probiotic cosmetic products in the Danish magazine "Kosmetik" (Forum, 2018) mentions that there are currently only two products containing live probiotic bacteria in the Danish market. According to the article, the term "probiotic" is used more broadly in cosmetics and includes ingredients that are not living but which have been obtained by means of probiotic bacteria such as lactic acid bacteria, also called *Lactobacillus* (Forum, 2018). The article divides "probiotic ingredients" in cosmetics into four "levels" or groups (Forum, 2018):

- Fermentation products or concentrates from fermentation. Probiotic bacteria are grown on a substrate and afterwards filtered out from the solution, but the solution still contains metabolites² from the bacteria. These metabolites may include antioxidants, amino acids or vitamins.
- 2. **Cell lysates** The broth of probiotic bacteria is not filtered, but the bacteria are destroyed so that cell contents and parts of cell walls are in solution.

¹ As an examples, the program of the conference contained presentations on "<u>New claims in skincare:</u> <u>anti-pollution and probiotic ingredients</u>" or "<u>Keep your skin flora happy</u>".

² Metabolites are intermediate substances that arise during biochemical transformation of substances in cells of living organisms (metabolism), e.g. in the metabolism of the bacteria.

- Tyndallization The probiotic bacteria are killed before use in the formulation. Thus, bacteria cannot propagate on the skin, but they can still bind to the skin's receptors and thus block access to pathogenic bacteria. This mechanism of action is called competitive inhibition.
- 4. **Living probiotic bacteria** Live bacteria are added to the cosmetic product with the purpose of colonizing the skin when the product is used.

According to stakeholder consultation, lactic acid bacteria, *Lactobacillus*, is the most used bacterial strain in the manufacture of cosmetics, followed by *Bifidobacterium*. A search for "Lactobacillus" in the CosIng database³ shows that there are over 350 ingredients related to the *Lactobacillus* genus. The ingredients related to *Lactobacillus* can be divided into four groups (INCI names are given in brackets):

- Lactobacillus bacteria (LACTOBACILLUS)
- Lactobacillus fermentation product (LACTOBACILLUS FERMENT)
- Lactobacillus fermentation product filtrate (LACTOBACILLUS FERMENT FILTRATE)
- Lactobacillus bacterial lysate (LACTOBACILLUS LYSATE)

The CosIng database lists a large number of different fermentation products whose names differ according to the substrate and the microorganisms that have been used for the production of the ingredient. The substrates usually consist of different plant species and parts. Apart from *Lactobacillus*, the following microorganisms often occur in the ingredient names: *Acetobacter, Aspergillus, Bacillus, Bifidobacterium, Lactococcus, Leuconostoc, Pediococcus, Saccharomyces, Streptococcus* and *Zygosaccharomyces*.

Many of these ingredients are labelled as skin conditioners or humectants in the CosIng database.

According to the stakeholder consultation, most products with probiotic claims contain "Lactobacillus ferment". In addition to *Lactobacillus*, the following microorganisms have been identified during the stakeholder consultation as well as an internet search on ingredient lists in cosmetic products on the Danish market:

- Bacillus
- Bifidobacterium
- Lactococcus
- Streptococcus
- Micrococcus.

It was noted that the metabolites (e.g. antioxidants, amino acids or vitamins) in fermentation products (first group of "probiotic" ingredients) are common ingredients in a variety of cosmetic products. In most cases, these ingredients do not lead to probiotic claims about the cosmetic products.

2.2.2 Prebiotic ingredients

Prebiotics are also known from their use as nutritional supplements in foods. Prebiotics act by inducing specific changes in the composition and/or in the activity of the intestinal microbiota, and thus have a beneficial effect on the health of the host.

Prebiotics in dietary supplements are short or long chain (possibly branched) carbohydrates made up of different types of monomers. The monomers are linked with bonds that cannot be

³ CosIng is the EU Commission's database on information on cosmetic ingredients. <u>https://ec.europa.eu/growth/sectors/cosmetics/cosing_en</u>

degraded by human digestive enzymes, but are rather metabolized and utilized by specific bacteria (Vignæs, 2012).

Specific requirements are imposed on a substance, if it is to be defined as a prebiotic dietary supplement. The following substances, which are used as dietary supplements and meet the requirements for non-digestion in the intestine, are recognized as prebiotics (Vignæs, 2012):

- fructans, which may be fructoligosaccharides or inulin
- galacto-oligosaccharides, consisting of galactose monomers
- lactulose, which is a disaccharide consisting of galactose and fructose.

An international research association has recently proposed to extend the definition of prebiotics in order to include more than strictly intestinal and dietary uses, as well as more substances in addition to the above-mentioned carbohydrates:

- conjugated linoleic acid
- polyunsaturated fatty acids
- polyphenols and phytochemicals.

Substances or substrates that are applied directly to the skin to give a positive health effect are thus also included in the proposed definition. The selective use of the substrate by certain microorganisms must be the cause of the health effects and the substrate must not be degraded by the host's own enzymes. According to this definition, the positive health effects should be documented through scientific studies (with animals or humans) before a substance or substrate can be recognized as prebiotic (Gibson et al., 2017).

In current applications in cosmetic products, the understanding of term "prebiotic" is less defined. A cosmetics manufacturer of prebiotic cosmetics products defines prebiotics on its website as follows: "Prebiotics are a food source for beneficial microbes to give them a competitive advantage. By giving them food, they proliferate and thrive, thereby excluding pathogenic (harmful) bacteria"⁴. According to the opinions of some of the contacted stakeholders, groups 1 - 3 of probiotic cosmetic ingredients as described in 2.2.1 should rather be referred to as "prebiotic" than "probiotic". Still, the ingredients from group 1 - 3 are also broader than the definition of prebiotics above (carbohydrates, conjugated linoleic acid, polyunsaturated fatty acids, polyphenols and phytochemicals).

As prebiotics in cosmetics, probiotic cell lysates or probioactives are often mentioned. These are degraded probiotic bacteria containing prebiotic substances (Dobos, 2017, stakeholder communications). The article in DermatologyTimes discusses the following ingredients as prebiotics in cosmetics: Cell lysates of probiotic bacteria containing hyaluronic acid, sphingo-myelinase (an enzyme), lipotechoinsyre (part of the cell wall of certain bacteria), peptidoglycan (part of the cell wall), lactic acid, acetic acid and diacetyl (Farris, 2016). In addition, some of the cosmetics manufacturers contacted mention the following ingredients: lactose, lactis proteinum (milk protein) and inulin.

For most of the mentioned ingredients INCI names (in capital letters) are available:

- fructooligosaccharides
- galactooligosaccharides
- ALPHA-GLUCAN OLIGOSACCHARIDE
- lactulose
- HYALURONIC ACID
- Sodium Hyaluronate
- LACTIC ACID

⁴ Anonymous.

- ACETIC ACID
- diacetyl
- LACTOSE
- LACTIS PROTEINUM
- MILK PROTEIN
- INULIN

Several of these ingredients are commonly found in cosmetic products (e.g. lactic acid and hyaluronic acid), and their presence can therefore not directly be linked to pro- or prebiotic claims of products. However, the stakeholder consultation and literature search also revealed that a few manufacturers claim their products as pro-/prebiotic solely based on these ingredients.

2.2.3 Raw materials for pro- or prebiotic cosmetics

According to stakeholder information, many cosmetics manufacturers have their own laboratories for the production of pro- or prebiotic ingredients. In addition, there are (bio-)chemical companies that develop pro- or prebiotic ingredients and supply the cosmetics manufacturers. For example, the chemical company BASF uses *Lactobacillus* in the manufacture of skin care and dental care products, as well as deodorants (Cosmetics Design Europe, 2017). According to the information the authors have been able to obtain in this project, there are currently no Danish suppliers of pro-/prebiotic ingredients for cosmetics. Some cosmetics manufacturers indicate that the range of raw materials is still quite limited but growing.

2.2.4 Relevant product types

The internet search and communication with stakeholders show that pro- and prebiotic claims are mainly used for facial skin products. These mainly include leave-on products (products that are applied to the skin and remain there), as well as a few rinse-off products (products washed off after application, such as facial scrubs, shampoo and hand soap).

Pro- and prebiotic products typically focus on certain "skin problems" such as redness, skin irritation or skin diseases such as acne. Claims are also made that the products prevent aging and inflammation or are particularly suitable for sensitive skin. According to stakeholder communication, the positive effects of pro-/prebiotic ingredients are documented in the scientific literature.

It is noted that there are many other products that are also claimed to remedy the aforementioned "skin problems", but which are not marketed as pro- or prebiotic cosmetic products.

2.2.5 Preservatives in pro- or prebiotic cosmetics

If a cosmetic product intentionally contains living bacteria, the opportunities for adding preservatives are limited, since the preservatives may kill the desired bacteria. However, since the vast majority of cosmetic products with pro-/prebiotic claims do not contain living bacteria, there is generally no difference in the addition of preservatives between pro- or prebiotic cosmetics and cosmetics. Chapter 3 compares the durability between pro-/prebiotic cosmetics and other cosmetics in order to detect differences in shelf life duration.

According to stakeholder information, the presence of living bacteria in a cosmetic product requires a highly selective preservation system. Otherwise, no information was obtained on specific preservatives and/or selective preservative systems in pro- or prebiotic cosmetics.

A few cosmetic products from a single manufacturer which are available on the Danish market via internet retailers and which contain living bacteria contain no substances identified as preservatives. Information on the shelf life or recommended storage temperature for these products was not available. When using products containing living microorganisms, the consumer should be aware that the product should not be combined with another (conventional) product that contains preservatives, as the preservatives may have an inhibitory effect on the living probiotic bacteria (Forum, 2018a, personal communication).

2.2.6 Market information on pro- and prebiotic cosmetics

Pro- and prebiotic cosmetic products are available through cosmetics retailers (in physical stores and/or via online shops) or directly from cosmetics manufacturers online. Some manufacturers market entire skin care series as pre-/probiotic while others just market specific products, e.g. skin types, as pro- and/or prebiotic.

Several stakeholders (personal communication) indicate that the pro- and prebiotic products are priced at the same level as other special or luxurious cosmetic products. Furthermore, they follow the same pricing rules as cosmetic products in general. Since many pro- and prebiotic products are new and specially developed, they are often found on the high end of the scale of prices. One manufacturer indicates that the price of the cosmetic product is also dependent on the content/concentration of the pro- or prebiotic ingredients.

According to information from the stakeholders, pro-/prebiotic products are still niche products, available only to a limited extent in physical stores. Therefore, they represent a small portion of the total turnover of skin care products (<1%). A number of convenience stores (discounters and supermarkets) state that they currently do not offer any cosmetic products with pro- or prebiotic claims.

Pro- and prebiotic products may, however, be found in department stores, in specialized cosmetics retailers, or in pharmacies. A larger selection is available through internet retailers. Communication with the stakeholders and searches on retailers' online shops also indicated that more pro- or prebiotic products may be available from a store's online shop than from the shelf in the physical store of the same retailer. Some of the pro- and prebiotic products are marketed specifically to cosmetologists.

During stakeholder consultation and internet search, 16 brands⁵ of products with pro- or prebiotic claims available through Danish retailers have been identified. Only four of these brands are available in physical stores (department stores or cosmetics retailers).

⁵ Retailer and brand names are not listed in this report, as requested by the Danish Environmental Protection Agency. However, the Danish EPA is familiar with the names.

3. Market investigation

The objective of the market study was to identify cosmetic products claimed to have pro- and prebiotic qualities at retailers in order to: i) estimate the market share of cosmetic products with pro- and prebiotic claims ii) assess whether these products differ in price or shelf life as compared to conventional products, iii) investigate if the products are labelled with ecolabels for environmentally friendly cosmetics, and; iv) survey which claims are used to promote the products (see also Chapter 4).

3.1 Method

3.1.1 Extract from the database Kemiluppen

The Danish Consumer Council Think Chemicals launched the app "Kemiluppen" in December 2015, allowing consumers to scan the barcode of cosmetic products with their smartphone. The product is subsequently assessed based on its constituents by the Consumer Council Think, resulting in an overall assessment of the product's contained substances and recommendations for consumers⁶.

In the database, it is possible to search for products by ingredients. The extraction of products with certain ingredients compared to the number of all products from the database may be used as an indication of the market share of certain cosmetic products.

However, the database does not contain information about claims of the products. Therefore, data on products with pro-/prebiotic claims cannot be extracted. Instead, an extract has been made of products containing ingredients that relate to the identified probiotic microorganisms:

- Lactobacillus
- Bacillus
- Bifid* (Bifido, Bifida, Bifidobacterium)
- Lactococcus
- Streptococcus
- Micrococcus.

Extracts have been made for products from the entire database, i.e. all product categories of cosmetic products are included.

3.1.2 Retailer survey

In this report, the term 'retailer' covers both internet retailers and physical stores. In the retailer survey, specific information on cosmetic products was collected:

- Product category
- Retailer
- Date of registration
- Volume (ml/g)
- Price
- Price per volume
- Shelf life, before and after opening
- Manufacturer (only for pro-/prebiotic products)
- Place of production (only for pro-/prebiotic products)

⁶ <u>http://kemi.taenk.dk/bliv-klogere/test-det-betyder-kolberne-b-og-c</u> (in Danish).

- Pro-/prebiotic ingredients (only for pro-/prebiotic products)
- Pro-/prebiotic claim(s) (only for pro-/prebiotic products)
- Ecolabel (Swan, EU Flower or EcoCERT; only for pro-/prebiotic products).

In order to compare results from the retailer survey with results from the Consumer Council Think Chemicals database, the same product categories as used in the database are used in the retailer survey. The database works with a category called "Cosmetics", which more specifically refers to make-up products. The category is therefore called "cosmetics/make-up" here.

Survey of products from internet Retailers

In the collection of information (Chapter 2), eight retailers were identified either having an online shop and physical stores (three retailers) or only sale via the internet (five retailers).

Subsequently, the eight internet retailers' websites were searched for more products with preor probiotic claims. Searches on the internet retailers' websites were conducted partly by searching specifically for brands and products identified in Chapter 2 (Section 2.2.6), as well as by searching for products with the following search terms:

- probiotisk
- probiotic
- probiotika
- præbiotisk
- præbiotika
- prebiotisk
- prebiotic.

Survey of products from a physical store

A single physical store (a department store) was chosen as an example of a physical store. In this shop, pictures were taken of all leave-on face care products from the following product categories:

- make-up remover/cleaning
- creams and lotions
- serums and oils
- skin tonic, mist, toner
- eye cream/eye serum.

These choices were made to concentrate the resources allocated to the project on the most relevant product categories with a certain probability of detecting products with pro-/prebiotic claims.

The products were photographed in May-June 2018.

3.2 Results from market research

3.2.1 Extract from the database Kemiluppen

At the time of the data collection (March 2018), the database contained 11,128 active products registered with separate barcodes. Throughout the database, 66 barcodes were found that included ingredients with the bacterially-derived names. This figure corresponds to 0.59% of all barcodes.

Some products are registered several times under different barcodes. The corrected number of products according to unique product names is 59. Six of the products contained more than one bacterially-derived ingredient. The results are summarized in TABLE 1 below. The data indicate that *Lactobacillus*, *Micrococcus* and *Bifidobacterium* are the most commonly used

bacteria for the formulation of cosmetic products. No products containing ingredients derived from *Streptococcus* were identified.

TABLE 1. Results from the consumer product database by bacterial names. Note that some products contain more than one bacterially-derived ingredient.

Active barcodes in total	11.128	
Number of barcodes with bacteria name	66	
% Number of barcodes with bacteria nan	0.59%	
Number of products with bacteria name		60
Number of barcodes per bacteria name	Lactobacillus	31
	Bacillus	1
	Bifid* (Bifido, Bifida, Bifidobacterium)	10
	Lactococcus	2
	Streptococcus	0
	Micrococcus	22

From TABLE 2 it becomes clear that the majority of products containing bacterially-derived ingredients is found in leave-on face care. Creams/lotions containing bacterially-derived ingredients constitute 20 products (33%), the largest group of products containing bacterially-derived ingredients. All face care products (49 products) make up 82% of the products with bacterially-derived ingredients (TABLE 2). Leave-on face products account for 86% of all face care products (provided that half of the products in the "Cleanser/ Makeup remover/ Wash" category are leave-on, and the masks, scrubs and peelings are rinse-off).

Category	Subcategory	Number of products with bacteria- derived in- gredient	% products out of the total number of products with bacteria- derived ingre- dient	Number of prod- ucts in total per (sub-) category	% products with bacteria- derived in- gredient out of all prod- ucts from the (sub-) cate- gory
Face care	In total	49	82%	1869	2.6%
	Cleanser/ Makeup re- mover/ Wash	10	16.7%	459	2.2%
	Cream / lotion	20	33.3%	765	2.6%
	Mask	1	1.7%	180	0.6%
	Scrubs/ peeling	1	1.7%	106	0.9%
	Serum	6	10.0%	89	6.7%
	Skin tonic/ toner/ mist	6	10.0%	180	3.3%
	Eye cream/ eye serum	5	8.3%	90	5.6%
Hair care	In total	4	7%	1237	0.3%
	Hair lacquer/ hair spray/ heat spray	1	1.7%	294	0.3%
	Hair foams	1	1.7%	74	1.4%
	Shampoo	2	3.3%	869	0.2%
Cosmetics/	In total	2	3%	243	0.8%
make-up	Mascara	1	1.7%	190	0.5%
	Primer / fixer	1	1.7%	53	1.9%
Body care	In total	5	8%	1179	0.4%
	Body lotion/ body cream	4	6.7%	806	0.5%
	Hand care	1	1.7%	373	0.3%
In total		60	100.0%	4528	1.3%

In the following table (TABLE 3), the numbers of registrations of individual products by consumers using the Kemiluppen app are summarized per category and expressed as number of scans. How often a product has been scanned can be seen as an indication of consumer interest in the product and provides information about the availability of the product. Half of the registered products with bacterially-derived ingredients are face creams and lotions (48%). In total, facial care products make up 90% of the scanned products, which again reflects the fact that facial care products are the most important product type in cosmetics containing bacterially-derived ingredients.

Category	Subcategory	Number of scans of prod- ucts with bacte- ria-derived in- gredient	% scans out of the total num- ber of scans of products with bacteria-derived ingredient
Face care	In total	22,514	90%
	Cleanser/ Makeup remover/ Wash	3,359	13.4%
	Cream/ lotion	12,035	48.0%
	Mask	745	3.0%
	Scrubs/ peeling	1,033	4.1%
	Serum	2,076	8.3%
	Skin tonic/ toner/ mist	1,535	6.1%
	Eye cream/ eye serum	1,731	6.9%
Hair care	In total	743	3.0%
	Hair lacquer/ hair spray/ heat spray	13	0.1%
	Hair foams	20	0.1%
	Shampoo	710	2.8%
Cosmetics/	In total	989	3.9%
make-up	Mascara / vipper	881	3.5%
	Primer / fixer	108	0.4%
Body care	In total	801	3.2%
	Body lotion/ body cream	645	2.6%
	Hand care	156	0.6%
In total		25,047	100%

TABLE 3. Number of scans per product category

Registrations in the database are driven by consumer interest in the products, but do not necessarily reflect that the products are also purchased correspondingly. In addition, it cannot be assumed that consumers who use the app for obtaining chemical information about cosmetic ingredients by scanning the products in stores are representative of cosmetic consumers in general.

Twenty-one different brands of products with bacterially-derived names were identified (TA-BLE 4). Most brands have only one product with a bacterially-derived ingredient (12 out of 21 brands), while only two brands have more than 10 products with bacterially-derived ingredients. Only two of the 16 brands identified in Chapter 2 are also found in the Consumer Council Think's database (brand names not shown).

The poor consistency between the brands identified in Chapter 2 and the database is likely to be explained by the following:

- Products in the database are typically registered by consumers in the stores. The majority of pro-/prebiotic products are not available in physical stores, but rather through internet retailers or through cosmetologists.
- In some cases, consumers register products which are not available through Danish retailers (e.g. during travel abroad or self-imported products).
- The content of bacterially-derived ingredients leads only in some cases to a pro-/prebiotic claim. Claims about specific products identified from the database have been checked on the retailers or manufacturers' websites. Nineteen of the 21 identified brands are not pro-

moted as being pro- or prebiotic. This shows that bacterially-derived ingredients are also added for reasons other than marketing.

• The database was established in 2015 and the data set used for this survey was from March 2018. Since products with pro-/prebiotic claims are relatively new, the likelihood that they have already been recorded in the database is smaller than for products that have been on the market for a longer time.

TABLE 4. Brands per number of products.

Brands per number of products with bacteria-derived ingredients Number of brands

Brands with 14 products	1
Brands with 13 products	1
Brands with 8-12 products	0
Brands with 7 products	1
Brands with 4-6 products	0
Brands with 3 products	2
Brands with 2 products	4
Brands with 1 product	12

3.2.2 Retailer survey

In the retailer survey, a total of 932 products (internet retailers + physical store) were investigated, of which 80 unique products had pro- and/or prebiotic claims.

Product types identified from internet retailers' websites

A total of 70 different products with pro- and/or prebiotic claims (distributed across 25 different brands) were identified from the eight selected internet retailers' websites.

The distribution of products by product type can be seen in Figure 1. Facial care products account for approximately two-thirds of the largest group of products.



Figure 1. Distribution of products with pro-/prebiotic claims from internet retailers by product type.

TABLE 5 shows how the products are distributed across subcategories. Most products are found in the subcategory of creams/ lotion and cleanser/ makeup remover.

Category	Subcategory	Number	Number with ecolabe
Face care		48	9
	Cleanser / Makeup Remover / Wash	11	2
	Creams and lotions	17	3
	Serums and oils	8	0
	Skin tonic / toner / mists	3	1
	Eye cream / eye serum	5	2
	Masks	4	1
Baby care		2	2
	Baby lotion / baby cream	1	1
	Baby oil	0	0
	Baby salve	0	0
	Baby shampoo	1	1
Cosmetics/Ma		2	0
	Blush / Highlighter	0	0
	Concealer / Corrector	0	0
	Lipstick/ Lipgloss / Lip liner	0	0
	Primer / Fixer	1	0
	Powder	1	0
Body care		8	5
	Body lotion / body cream	5	3
	Foot care	0	0
	Hand care	1	1
	Oils	1	1
	Salve / gel	0	0
Sun care		0	0
Hair care		2	2
	Balsam / conditioner / deep conditioner	1	1
	Shampoo	1	1
Soap and hyg		8	5
- sup and nye	Deodorant	4	2
	Intimate care		0
	Handsoap, liquid	1	1
	Body shampoo / body gel / foam bath / bath salts	2	1

TABLE 5. Number of products with pro-/prebiotic claims from internet retailers.

Product types identified in the department store

There was a total of 862 leave-on cosmetic products for facial care (distributed across 49 different brands) in the selected department store. Of these, 15 different products with proand/or prebiotic claims were identified (distributed across five different brands). Only one of the brands had not been identified in the survey of products from the internet retailers. The following table (TABLE 6) shows how products with pro-/prebiotic claims are distributed across subcategories within facial care. It is seen that most products belong to the subcategory "creams/lotions" and "serums and oils".

Category	Subcategory	Number	Number of products with pro-/prebiotic claims	% Number of products with pro-/prebiotic claims	
Ansigtspleje		862	15	1.7%	
	Cleanser / Makeup Re- mover / Wash	47	2	4.3%	
	Creams and lotions	446	4	0.9%	
	Serums and oils	205	8	3.9%	
	Skin tonic / toner / mist	45	0	0%	
	Eye cream / eye serum	115	1	0.9%	

TABLE 6. Number of products with pro-/prebiotic claims in the department store.

Pro- and prebiotic ingredients

The ingredient lists of the pro-/prebiotic products were reviewed for ingredients identified in Chapter 2. Twenty-three unique ingredients were found (TABLE 7). Most of the pro-/prebiotic products contain several of these ingredients. The most common ingredients, often found in combination, are: Alpha-Glucan Oligosaccharide, Inulin, Lactic Acid, and Lactobacillus Ferment/Lactobacillus. Most of the products with pro-/prebiotic claims (82%) contain at least one ingredient in which the name of a microorganism occurs (e.g. *Lactobacillus* ferment or *Saccharomyces* lysate extract).

TABLE 7. Pro-/prebiotic ingredients in the products with pro-/prebiotic claims (INCI names written in capital letters).

ALPHA-GLUCAN OLIGOSACCHARIDE
BIFIDA FERMENT LYSATE
Hansenula Ferment*
INULIN
Kloeckera Ferment*
LACTIC ACID
LACTIS PROTEINUM
LACTOBACILLUS
LACTOBACILLUS FERMENT
LACTOBACILLUS FERMENT LYSATE
LACTOBACILLUS/WATER HYACINTH FERMENT
LACTOCOCCUS FERMENT
LACTOCOCCUS FERMENT LYSATE
LACTOSE
LINOLEIC ACID
MILK PROTEIN
Pediococcus Ferment*
SACCHAROMYCES FERMENT
Saccharomyces lysate extract*
SODIUM HYALURONATE
SODIUM LACTATE
* Connot be found in the come wording in the Cooling database

* Cannot be found in the same wording in the CosIng database.

Comparison of prices

In Figure 2, the average prices are broken down by product category for products with pro-/prebiotic claims and 'conventional' products (in this context, understood as products without pro-/prebiotic claims). Prices at internet retailers and physical stores are not considered to be directly comparable; therefore, only products registered at the department store are included in the comparison.

The prices are in the same range. It is noted that the average price of the products with pro-/prebiotic claims is calculated from very few values, making a robust comparison impossible. The figures confirm, however, the information received through communication with stakeholders: significant differences in prices between pro-/prebiotic and conventional products are not expected.



Figure 2. Average prices of pro-/prebiotic and conventional products.

Comparison of durability

If a cosmetic product has a shelf life of 30 months or less, the minimum durability date must be stated on the packaging. The minimum durability date must be stated with either the hourglass symbol or the text: "Should be used by the end of...". For products with a shelf life over 30 months, the period after opening must be indicated with the required jar symbol⁷.

None of the investigated products showed a shelf life of less than 30 months, but for most products the shelf life after opening could be identified (TABLE 8). None of the products with pro-/prebiotic claims differed remarkably from other products (e.g. with short shelf lives). The comparison indicates that products with and without pro-/prebiotic claims do not differ in their durability.

The internet retailers typically only show a picture of the front of the packaging on their products' websites. Products from internet retailers were not purchased for further study and information for these products was therefore collected only from the websites. If durability symbols/- dates were printed somewhere other than on the front of the product, the information was not included on the websites.

		Period after opening (months)					
		3	6	9	12	18	24
Normalis and a second sector	With pro-/prebiotic claims		1	1	9		3
Number of products	'conventional'	3	173	34	284	59	95

TABLE 8. Comparison of durability of products per category identified in the department store.

⁷ <u>https://mst.dk/kemi/kemikalier/regulering-og-regler/faktaark-om-kemikaliereglerne/maerkning-af-kosmetik/</u> (in Danish)

Ecolabelling

Ecolabel criteria for environmentally- and/or health-friendly cosmetic products are available from the Nordic Swan Standard⁸, the EU flower (only for rinse-off cosmetics)⁹ and ECOcert¹⁰ (private global certification company). None of these labelling schemes have criteria related to the use of microorganisms or bacteria-derived ingredients in cosmetic products.

In the retailer survey, it was noted whether the products were labelled with one or more ecolabels, i.e. the EU flower, the Nordic Swan or the ECOcert symbol. About one third of the products with pro-/prebiotic claims was labelled (29 %, 23 of 80 unique products). All 23 labelled products were labelled with ECOcert and a few products, available in the department store, were also labelled with the Nordic Swan.

It should be noted that the internet retailers typically only show a picture of the front of the packaging on their websites. Products from internet retailers were not purchased for further study and information for these products was, therefore, collected only from the websites. If an ecolabel is printed on the back of the product, it was not available for this study (for the same reason as described above for durability).

⁸ Swan critera document, 2018: <u>http://www.nordic-ecolabel.org/product-groups/group/?productGroupCode=090 (in Danish)</u>

⁹ EU flower criteria document, 2014: <u>https://eur-lex.europa.eu/legal-</u> content/EN/TXT/PDF/?uri=CELEX:32014D0893&from=EN

¹⁰ ECOcert standard criteria document, 2012: <u>http://www.ecocert.com/sites/default/files/u3/Ecocert-</u> <u>Standard/index.pdf</u>

4. Claims of pro-/prebiotic cosmetics

This chapter describes the rules and requirements for claims made for cosmetic products in accordance with the Cosmetics Regulation (section 4.1). In addition, the specific health-related claims that are used in the marketing of the pro-/prebiotic cosmetic products identified in this survey are described (section 4.2).

4.1 Generally about claims of cosmetic products

In the Cosmetics Regulation¹¹ Chapter VI on Consumer Information, Article 20 provides rules about claims for cosmetic products. Here, it appears that a cosmetic product available on the market or in the context of advertising must not be subject to statements that imply product characteristics or functions which the product does not have (Article 20, paragraph 1 of the Cosmetics Regulation). This rule includes both labelling on the products' packaging and all forms of marketing material, and applies to text, names, trademarks, pictures and symbols that may mislead the consumer to believe that the product has properties that it does not. On the basis of Article 20 (2) of the Cosmetics Regulation, the Cosmetics Claims Regulation¹² has adopted a list of common criteria for claims that may be applied to cosmetic products.

The Cosmetics Claims Regulation states that the so-called responsible person has to ensure that the wording of the product's claim complies with the common criteria set out in Annex I of the Cosmetics Claims Regulation. In addition, the responsible person must ensure that the claims are substantiated by documentation in the dossier containing product information for the cosmetic product referred to in Article 11 of the Cosmetics Regulation.

Annex I of the Cosmetics Claims Regulation sets out six common criteria for claims about cosmetic products. The first criterion concerns *legal compliance:*

- Claims that indicate that the product has been authorised or approved by a competent authority within the Union shall not be allowed.
- The acceptability of a claim shall be based on the perception of the average end user of a cosmetic product, who is reasonably well-informed and reasonably observant and circumspect, taking into account social, cultural and linguistic factors in the market in question.
- Claims which convey the idea that a product has a specific benefit when this benefit represents mere compliance with minimum legal requirements shall not be allowed.

The second criterion requires the truthfulness of the claims:

- If it is claimed that the product contains a specific ingredient, the ingredient shall be deliberately present.
- Ingredient claims referring to the properties of a specific ingredient shall not imply that the finished product has the same properties when it does not.
- Marketing communications shall not imply that expressions of opinions are verified claims unless the opinion reflects verifiable evidence.

¹¹ Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.

¹² Commission Regulation (EU) No 655/2013 of 10 July 2013 establishing common criteria for the substitution of claims for cosmetic products.

The third criterion requires evidential support for the claim, including:

- Claims used must be supported by adequate and verifiable documentation.
- Evidence for claim substantiation must take into account state of the art practices.
- If studies are used as documentation, they shall be relevant to the product and the benefit claimed, and they shall follow well-conducted methodologies and respect ethical considerations.
- Statements of clear exaggeration which are not to be taken literally by the average end user shall not require substantiation.
- A claim extrapolating (explicitly or implicitly) ingredient properties to the finished product shall be supported by adequate and verifiable evidence.
- Assessment of the acceptability of a claim shall be based on the weight of evidence of all studies, data and information available depending on the nature of the claim and the prevailing general knowledge the end users.

The fourth criterion deals with honesty:

- Presentations of a product's performance shall not go beyond the available supporting evidence.
- Claims shall not attribute to the product's specific (i.e. unique) characteristics if similar products possess the same characteristics.
- If the action of a product is linked to specific conditions, such as use in association with other products, this shall be clearly stated.

The fifth criterion deals with the fairness of the claim, which is elaborated as:

- Claims must be objective and must not constitute competitors or ingredients used legally.
- No claims may be used that may give rise to confusion with a competing product.

The sixth and final criterion deals with *informed decision-making*, including:

- Claims must be clear and understandable to the average end user.
- Claims should be seen as an integral part of the product and must contain information that allows the average end user to make an informed choice.
- Marketing needs to take into account the target audience, its ability to understand the message and that information in that regard must be clear, precise, relevant and understandable to the target audience.

The common criteria are summarized in an indicative technical document¹³ that is regularly updated and contains specific and illustrative examples of how the criteria should be understood in relation to specific claims.

The assessment of whether a claim complies with applicable requirements is based on the perception and expectations of the consumers towards the product, including those resulting from the claim.

4.2 Claims of pro- and prebiotic cosmetic products

This survey focused on how cosmetic products are marketed with "prebiotic" or "probiotic" claims as described below. It was out of the scope of the survey to assess whether claims and the underlying documentation for possible effects live up to good practice for claims in cosmetics. As described in Chapter 2, the terms "probiotic" and "prebiotic" are neither well-defined nor distinguished as regards cosmetic ingredients or claims of cosmetic products. Therefore, there is no distinction between "probiotic" and "prebiotic" claims in this section.

¹³ "Technical document on cosmetic claims": <u>https://ec.europa.eu/docsroom/documents/24847</u>

In the retailer survey, some cosmetics brands were identified that market the entire product's series as pro- or prebiotic, for example, by using the label "Probiotic Skincare" as part of the brand logo. However, there are often some products in the series that do not contain pro- or prebiotic ingredients, e.g. pure oils.

Most brands have a single product or a few products marketed as pro- or prebiotic in a skin care series. The claim is typically displayed on the product description printed on the packaging or displayed on the retailer's product website, or is part of the product/brand name that appears on the front of the packaging (e.g. "[brand name] Probiotic cleanser").

The claims of the identified products were analysed and divided into six groups depending on the health-related claim (TABLE 9). The vast majority of claims relate to positive effects on the skin and most products are claimed to have several effects.

Claim group by effect	Description	Examples of claims within the group
Skin problems	Claim to counteract or remedy skin problems such as red- ness, irritated skin, or swell- ing.	Claim on a face cream on the packaging: " cream with probiotic technology Extra-gentle, oil-free moisturizing cream suitable for skin with per- sistence or reactive redness. Instantly comforts and soothes. Relieves the appearance of visible redness, soothes to cool discomfort and quells blotchiness to restore a more even skin tone. "
Skin diseases	Claim to counteract or remedy skin disorders such as acne, psoriasis or rosacea.	Claim on a make-up remover from a product website: " <i>Prebiotics stimulates the formation of the good bac-</i> <i>teria and helps fight the bacteria that make unclean</i> <i>skin and acne</i> " [translated from Danish]
Skin type	Claim to be particularly suita- ble for certain skin types, such as sensitive skin, oily skin and/or dry skin.	Claim on a body lotion from a product website: " Probiotic strengthens the cells' detoxification pro- cess and normalizes skin pH recommended for dry and delicate skin, both for children and adults. " [translated from Danish]
General positi- ve health ef- fects	Claim to cause general posi- tive health effects on the skin, e.g. better skin balance, mois- turizing, softening, strength- ening the skin's defense mechanisms, stimulating and/or calming.	Claim on a face serum from a product website: "Probiotic technology helps strengthening and pro- tecting the skin against external aggressions by pro- moting hydration." [translated from Danish] Claim on a face cream from a product website: "Revolutionary double-acting, multiuse enzyme polish that transforms and lightens dull, rough, clogged and energy-reduced skin. Comprising probiotics and peptide complex that balances and protects the skin, and 100% pure bio-organic oil that emulsifies upon contact with water." [translated from Danish]
Aging	Claim to counteract skin ag- ing, e.g. slow down the aging process, make wrinkles and lines less visible.	Claim on a face serum from a product website: " Inactivated probiotic Lactobacillus cells are added to stimulate the skin's production of ß-defensins. These peptides change the micropopulation of the skin in a way that favors the beneficial strains so that they can compete with the aging strains." [translated from Danish]

TABLE 9. Breakdown of claims in groups by related effects.

Microorganisms	Claim to affect the composi- tion of the skin's microorgan- isms.	Claim of a bodylotion from a product website: "Prebiotic * - Helps restore the beneficial microflora in the skin of the child " [translated from Danish] Claim of a deodorant o from a product website: "Prebiotics inhibit the bacteria that cause bad body
		<i>odor</i> " [translated from Danish] Claim a face cream from a product website.
		"Prebiotics favor the growth of beneficial microbes. Probiotics contain an extract of probiotic Lactobacil- lus species. The extract will increase the amount of beneficial microbes on the skin. " [translated from Danish]

Most of the pro-/prebiotic claims also emphasize some general positive health effects associated with the pro-/prebiotic ingredients, such as "moisturizing" or "strengthening the skin's defense mechanisms". These claims, however, are not specific to products with pro-/prebiotic claims, but are generally found for many cosmetic skin products.

For 17 out of the 80 products with pro-/prebiotic claims (Section 3.2.2) it is indicated that the pro-/prebiotic ingredients have an effect on the skin's bacterial flora, usually either by promoting beneficial bacteria or by inhibiting harmful bacteria (TABLE 10). Comparing the claim type and ingredients, no clear pattern between occurrence of certain ingredients and claiming of certain effects was identified.

Claim group by effect	Number of products within the claim group	Pro-/prebiotic ingredients (number of products)*
Skin problems	19	Alpha-Glucan Oligosaccharide (5)
		Inulin (5)
		Lactobacillus Ferment (4)
		Lactobacillus (3)
		Bifida ferment lysate (2)
		Lactis Proteinum (2)
		Lactic acid (2)
		Hansenula Ferment (1)
		Kloeckera Ferment (1)
		Lactococcus Ferment (1)
		Leuconostoc Ferment (1)
		Pediococcus Ferment (1)
		Saccharomyces Ferment (1)
		[Ingredients list not available] (1)
Skin diseases	6	[Ingredients list not available] (3)
		Lactobacillus Ferment (2)
		Alpha-Glucan Oligosaccharide (1)
		Hansenula Ferment (1)
		Kloeckera Ferment (1)
		Lactococcus Ferment (1)
		Leuconostoc Ferment (1)
		Pediococcus Ferment (1)
		Saccharomyces Ferment (1)
Skin type	8	Lactobacillus Ferment (4)
	0	[Ingredients list not available] (3)
		Inulin (2)
		Lactic Acid (2)
		Sodium Hyaluronate (2)
		Alpha-Glucan Oligosaccharide (1)
		Lactobacillus (1)
	F4	
General positive health effects	51	[Ingredients list not available] (14)
		Inulin (11)
		Alpha-Glucan Oligosaccharide (10)
		Lactobacillus Ferment (10)
		Lactic Acid (9)
		Lactobacillus (9)
		Bifida ferment lysate (6)
		Sodium Hyaluronate (6)
		Lactis Proteinum (5)
		Lactose (4)
		Lactoccus ferment lysate (3)
		Lactobacillus ferment lysate (2)
		Hyaluronic Acid (1)
		[No pro-/prebiotic ingredient identified] (1)
		Saccharomyces Ferment (1)
		Saccharomyces lysate extract (1)
		Sodium Lactate (1)
		Hansenula Ferment (1)

TABLE 9. Number of products with claims about effects related to content of pro-/prebiotic	;
ingredients.	

		Kloeckera Ferment (1)
		Lactococcus Ferment (1)
		Leuconostoc Ferment (1)
		Pediococcus Ferment (1)
Aging	12	[Ingredients list not available] (5)
		Alpha-Glucan Oligosaccharide (2)
		Bifida ferment lysate (2)
		Inulin (2)
		Lactis Proteinum (2)
		Lactobacillus Ferment (2)
		Sodium Hyaluronate (2)
		Lactic Acid (1)
		Lactobacillus (1)
		Lactose (1)
Microorganisms	17	Alpha-Glucan Oligosaccharide (12)
		Inulin (9)
		Lactobacillus (6)
		Lactobacillus Ferment (5)
		Lactic Acid (5)
		[Ingredients list not available] (3)
		Sodium Hyaluronate (3)
		[No pro-/prebiotic ingredient identified] (1)

* Many cosmetic products contain more than one pro-/prebiotic ingredient. The sum of the number of products indicated in this column is therefore greater than the number given in column "Number of products within the claim group".

5. Conclusion

Several stakeholders recognize pro- and prebiotic cosmetics as "trendy" and the market is considered to be growing. Therefore, an increasing number of products with pro- and prebiotic claims are expected in the future.

In the light of results from stakeholder consultation, literature/internet search, the consumer product database and the retailer survey, the overall conclusion is that there is no clear correlation between pro-/prebiotic claims and pro-/prebiotic ingredients in cosmetics.

Ingredients

Pro- and prebiotic ingredients are used as dietary supplements, and the definitions of the concepts are basically developed from their use as dietary supplements, where the term probiotic refers to in living microorganisms.

In cosmetics, the terms are used more broadly. Ingredients that lead to pro-/prebiotic claims are broader in cosmetic applications than for dietary supplements. The definition of "probiotic" involves the use of living microorganisms having a beneficial effect on the host whereby the effect can be documented. However, living microorganisms are only used to a limited extent in cosmetic products. In cosmetics, however, a number of ingredients which are produced by microorganisms are referred to as 'probiotic'.

The INCI names of these ingredients often refer to the genus name (e.g. "*Lactobacillus*") followed by one or more of these terms: "ferment", "lysate", "filtrate", "extract" (e.g. "*Lactobacillus* ferment lysate"). Microorganisms used in the preparation of probiotic ingredients may, for example, include:

- Lactobacillus (most used)
- Bacillus
- Bifidobacterium
- Lactococcus
- Streptococcus
- Micrococcus.

The definition of "prebiotic" substances implies that the substances result in specific changes in the composition and/or the activity of the host's microbiota, that the substances cannot be degraded by the host's own enzymes, that they have a beneficial effect on the health of the host and that the effect can be documented. In cosmetics, however, prebiotic ingredients are less defined, i.e. they are referred to as substances that can be exploited by beneficial bacteria or as substances produced using microorganisms (see probiotic ingredients). Prebiotic ingredients may include (INCI names in capital letters):

- fructooligosaccharides
- galactooligosaccharides
- ALPHA-GLUCAN OLIGOSACCHARIDE
- lactulose
- HYALURONIC ACID
- Sodium Hyaluronate
- LACTIC ACID
- ACETIC ACID
- diacetyl
- LACTOSE
- LACTIS PROTEINUM

- MILK PROTEINUM
- INULIN.

Alpha-Glucan Oligosaccharide, Inulin, Lactic Acid, and Lactobacillus Ferment/Lactobacillus are the ingredients most commonly found in products with pro-/prebiotic claims in the retailer survey. Extracts from the consumer product database also showed that ingredients produced using *Bifidobacterium* and *Micrococcus* are often present.

Many cosmetics manufacturers have their own laboratories for the production of pro- or prebiotic ingredients.

In addition, there are (bio-)chemical companies that develop pro- or prebiotic ingredients. According to the information obtained in this survey, there are currently no Danish suppliers of pro-/prebiotic ingredients for cosmetics. Some cosmetics manufacturers indicate that the range of raw materials is still quite limited but growing.

A number of the above-mentioned ingredients (e.g. Sodium Hyaluronate, LACTIC ACID) are widely used in cosmetic products and their use is by no means limited to products with pro-/prebiotic claims. In contrast, there are also some of the ingredients identified during data and information collection and from the consumer product database which were not found in any of the products with pro-/prebiotic claims in the retailer survey (e.g. diacetyl, *Micrococcus*). Some products with pro-/prebiotic claims in the retailer survey contain no pro-/prebiotic ingredients at all. This means that a pro-/prebiotic claim can be used as an indication of pro-/prebiotic ingredients, but that there is no clear relationship between claims and ingredients.

Product types

Both stakeholder communications and the survey of products from internet retailers show that the products with pro-/prebiotic claims are primarily leave-on products (for example, face cream or body lotion) and include only a few rinse-off products (for example, facial scrubs or hand soap).

Products with pro-/prebiotic claims are mainly for facial care (69%). In addition, some body care products (11%), soap and hygiene (11%) and a few baby care, hair care and cosmetics/make-up products (3% in each category) were identified. This distribution is in accordance with the stakeholder findings that the product should remain on the skin so that the pro-/prebiotic ingredients can have an effect.

Market shares of products with pro-/prebiotic claims

A limited overview of the market and market shares in pro-/prebiotic cosmetics in Denmark is available. Several stakeholders estimate that these products are still niche products and that the market share is <1% (in turnover).

The products are not yet available in convenience stores (discount markets and supermarkets), but are available in department stores, specialized cosmetics retailers, or pharmacies. A significantly larger selection is available through the internet retailers. A number of products are marketed specifically to cosmetologists.

The data on cosmetic products containing bacterially-derived ingredients from the consumer products database revealed a fraction of only 0.59% of products containing bacterially-derived ingredients. The data extraction showed that *Lactobacillus*, *Micrococcus* and *Bifidobacterium* are the most commonly used bacteria in the names of the bacterially-derived ingredients. However, no products with pro-/prebiotic claims were found to contain a *Micrococcus* ingredient in the retailer survey. This exemplifies the fact that there are products which contain bacterially-derived ingredients, but which are not marketed with pro-/prebiotic claims. In contrast, there are also products that do not contain pro-/prebiotic ingredients, but still are marketed

with probiotic/prebiotic claims. In the survey of the products in the department store, the number of the pro-/prebiotic claimed products accounted for 1.7% of all products in the facial care category. This is in line with the stakeholder's estimate of <1%, taking into consideration that pro-/prebiotic products are niche products and sold to a lesser extent than other products and that the retailer survey investigation was limited to internet retailers and a department store where products with pro-/prebiotic claims are actually sold. As mentioned above, they are not sold in more common convenience stores such as supermarkets.

The market share estimated from the consumer product database is smaller than the estimate from the retailer survey. This is to be expected, since the database covers all cosmetic product categories and all products from all retailers of cosmetic products (including convenience stores). In the retailer survey in this study, neither any convenience stores (only a department store) nor all product categories (only leave-on facial care) were included.

Durability, pricing and eco-labelling

Prices of products with pro- and prebiotic claims are in line with other specially developed cosmetic products. The comparison of shelf lives show that products with and without pro- and prebiotic claims do not differ from others. This finding is in line with information from stake-holders that products with pro-/prebiotic claims (usually) not contain living microorganisms and therefore no difference in durability is to be expected. About one third of the products with pro-/prebiotic claims were labelled with the ECOcert label. In addition, some products from the department store were labelled with the Nordic Swan ecolabel.

Claims

Claims such as "probiotic", "prebiotic" or the like are typically available from the product description and printed on the packaging or displayed on the internet retailer's product website, or are a part of the product/brand name that appears on the front of the packaging.

Most of the claims relate to some general positive health effects in skin and/or relate to alleviate skin disorders and/or conditions. Claims about effects relating to changes in the skin's natural bacterial communities seem to differentiate pro-/prebiotic cosmetics from other cosmetics.

Comparison of the various claimed health effects and ingredients has indicated no clear pattern between occurrence of ingredients and claims about certain effects.

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Survey of cosmetic products with "probiotic" or "prebiotic" claims

The study provides more knowledge about pro / prebiotic cosmetics in Denmark with regard to ingredients, products and market overview. Pro and prebiotic ingredients are well known as dietary supplements, and their definition is based on their use in food / dietary supplements. The common definition of "probiotic" involves the use of living microorganisms with a beneficial proven effect on the host. However, the study showed that living microorganisms are used only to a limited extent in cosmetic products. Nonetheless a number of ingredients produced by microorganisms are referred to as "probiotic". Branch contacts estimate that pro- and prebiotic claimed products are still niche products and the market share is below 1%. In a retailer survey 932 products were included, of which 80 unique products were with pro- and/or prebiotic claims. The products were mainly for facial care and were found in department stores, which primarily led specialty and luxury cosmetics, or at pharmacies. A significantly larger selection was available through internet retailers. Products claimed as pro- and prebiotic are similarly priced as other specialty cosmetic products, and do not differ from other cosmetics with regard to preservation and durability. Typically, the claim as "probiotic", "prebiotic" or the like, appears in the product description printed on the packaging, the internet retailer's product homepage, or is part of the product/brand name printed on the packaging, and most of them relate to general positive health effects in the skin, e.g. to create "better balance" or "moisturizing".



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