



National Institute for Public Health
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Ministry of Health, Welfare and Sport

Microbial cleaning products: an inventory of products, potential risks and applicable regulatory frameworks

RIVM letter report 2020-0160
L. Razenberg et al.



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Colophon

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Synopsis

Microbial cleaning products: an inventory of products, potential risks and applicable regulatory frameworks

Microbial cleaners are cleaning agents containing bacteria. These can be cleaning agents for use in and around the home, as well as personal care products for cleaning your skin or hair. Examples are all-purpose cleaners and shampoo with added bacteria. The bacteria are for example added because they produce enzymes that can break down dirt or stains. The packaging of microbial cleaners often states that the product is safe, natural and free of chemicals.

RIVM has carried out a general survey of which microbial cleaners are offered for sale in the Netherlands. In total, 92 products were identified. For each product, information was collected about which type of bacteria it contained and how it should be used. RIVM prepared this overview at the request of the Netherlands Food and Consumer Products Safety Authority (NVWA). The goal was to obtain more insight into these products, what they are used for and their potential health risks.

Microbial cleaners may be covered by different pieces of legislation. For example by the legislation for cleaning agents (detergents), for personal care products (cosmetics), or for agents that are used to combat harmful organisms (biocides). Specific safety requirements on bacteria in microbial cleaners are only set in the legislation on biocides. Appropriate legislation is therefore necessary when examining the safety of these cleaners.

If people come into contact with bacteria from a microbial cleaner, they can develop symptoms such as a skin rash or an allergic reaction as a result. In order to assess the safety of a microbial cleaner, information is needed about the characteristics of the bacterial species that it contains. Information is also needed on how people come into contact with the bacteria and how frequently this occurs. For many microbial cleaners, this information is not available because there is no adequate legislation requiring this. It is therefore more difficult to assess the risk. The manufacturer is always responsible for ensuring that a product is safe.

Keywords: microbial cleaners, bacteria, Bacillus, biocides, detergents, cosmetics

Publiekssamenvatting

Microbiële reinigers: een inventarisatie van producten, mogelijke risico's en geldende wetgeving

Microbiële reinigers zijn schoonmaakmiddelen met bacteriën erin. Dat kunnen schoonmaakmiddelen voor in en om het huis zijn, maar ook verzorgingsproducten om je huid of je haar schoon te maken. Voorbeelden zijn allesreinigers en shampoo met toegevoegde bacteriën. De bacteriën worden bijvoorbeeld toegevoegd omdat ze enzymen produceren die vuil of vlekken kunnen afbreken. Op de verpakking staat vaak dat de microbiële reiniger veilig, natuurlijk en vrij van chemische stoffen is.

Het RIVM heeft op hoofdlijnen in kaart gebracht welke microbiële reinigers in Nederland te koop zijn. Er zijn 92 producten gevonden. Voor elk product is informatie verzameld over welke soort bacterie erin zit en hoe je het moet gebruiken. Het RIVM heeft dit overzicht gemaakt in opdracht van de Nederlandse Voedsel- en Warenautoriteit (NVWA). Het doel was om meer zicht te krijgen op deze producten, waar ze voor zijn en welke risico's voor de gezondheid ze kunnen hebben.

Microbiële reinigers kunnen onder verschillende wetgeving vallen. Bijvoorbeeld onder de wetgeving voor schoonmaakmiddelen (detergenten), voor verzorgingsproducten (cosmetica) of voor middelen die schadelijke organismen bestrijden (biociden). Alleen de biocidenwetgeving stelt specifieke veiligheidseisen aan bacteriën in microbiële reinigers. Om te toetsen of deze reinigers veilig zijn, is dus passende wetgeving nodig.

Als mensen in aanraking komen met bacteriën uit een microbiële reiniger, kunnen ze daar klachten van krijgen zoals huiduitslag of een allergische reactie. Om de veiligheid van een microbiële reiniger te schatten, is onder andere informatie nodig over de eigenschappen van de bacteriesoort die erin zit. Ook moet bekend zijn hoe (inslikken, inademen of op je huid krijgen) en hoe vaak mensen met de bacteriën in aanraking komen. Voor veel microbiële reinigers ontbreekt deze informatie omdat er geen passende wetgeving is die dat vraagt. Daarom is het moeilijk om het risico te schatten. Wel is de fabrikant er in alle gevallen voor verantwoordelijk dat een product veilig is.

Kernwoorden: microbiële reinigers, bacteriën, Bacillus, biociden, detergenten, cosmetica.

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Summary

Chemical cleaning products that contain surfactants to remove dirt or stains are often used for cleaning. As an alternative, microbial cleaning products that contain microorganisms in order to remove dirt, stains and/or unwanted odours can be used. Little is known about the types of microbial cleaning products available on the Dutch market and their potential risks. The aim of this project was therefore to provide an overview of the product group of microbial cleaning products and their composition. In addition, the project aims at giving an overview of the potential risks, of the regulatory frameworks that could be applicable and of the information required to perform a risk assessment for the exposure to microorganisms present in microbial cleaning products.

A search for microbial cleaning products available on the Dutch market resulted in 92 products and showed a wide variety of different microbial cleaning products. Information available on the commercial websites about the intended use, application form, claims, microorganism(s) present and chemical composition was recorded. Most of these products could be grouped into household cleaners, personal care products and animal and garden related cleaning products. The search also showed a number of other products, such as a cleaning spray for face masks, air conditioner cleaning products, a waterbed conditioner and drain-unblocking products. For many of the products the available information was limited, especially for the microorganisms and chemical composition of the products. Products for which such information was available, all contained bacteria, in particular *Bacillus* species. Products containing other microorganisms (such as phages, yeasts or moulds) were not found. Information about the chemical composition was mainly available for personal care products (due to legal requirements for cosmetic products). All information found about preservatives in the products, showed that only allowed substances were used. Microbial cleaning products were often found to be marketed as natural, free from chemicals and environmentally friendly. Products were advertised as being safe for human and animal health and sometimes even as improving health and hygiene. Many products claimed to have a fast, thorough and/or long-lasting effect.

Regulatory frameworks set the requirements for placing a product on the market, including notification or authorisation and set restrictions on the use of harmful ingredients and requirements for labelling and packaging. Microbial cleaning products may fall within the scope of the frameworks on detergents, on cosmetics, on biocidal products and the more general Commodities Act. Which framework applies depends, amongst others, on the presence of a biocidal claim. For products for which the applicable regulatory framework is not clear, their status is subject to discussion. These products are called borderline products. Recent legal ruling and European developments might help to clarify the status of microbial cleaning products in the future.

The Biocidal Products Regulation includes specific data requirements for the microorganisms present in the products. Under the regulatory frameworks on detergents and on cosmetics, the only requirements are to include the

microorganism in the list of ingredients and a general requirement that products on the market should be safe under normal conditions of use.

Microorganisms added to microbial cleaning products may pose a risk to humans, animals and the environment. Hazards of microorganisms include infection, intoxication, irritation or hypersensitivity reactions and the development of contact allergy. The *Bacillus* species found may cause irritation reactions when exposure via eyes, skin or inhalation occurs. They may also lead to the development of contact allergy after exposure via skin or via inhalation. One product unintendedly contained *Bacillus cereus*, a pathogenic species that may lead to intoxication after oral exposure. This shows that contamination of a microbial cleaning product with unwanted *Bacillus* species could be a serious problem. Further, the (environmental) spreading of antimicrobial resistance genes is a hazard that can be related to microorganisms (including the *Bacillus* species found in microbial cleaning products). Depending on the product and its use, exposure potentially occurs via skin contact, ingestion or inhalation. Whether a risk arises or not, depends on the properties of the microorganism present and the exposure (both exposure route and amount of exposure). Based on the hazards and the relevant exposure routes, the potential risks for the *Bacillus* species found in microbial cleaning products are irritation of eyes, skin or respiratory tract and the development of contact allergy.

In order to assess the safety of a microorganism related to the use of a specific microbial cleaning product, a safety assessment method is required. Such a method is currently not in use for microbial cleaning products falling within the scope of the Regulation on Detergents or the Regulation on Cosmetic Products. In several other regulatory frameworks, including frameworks for food and feed, for biocides and for plant protection products, methods for risk assessment of microorganisms are developed and in use. The requirements for microorganisms are similar in the three regulatory frameworks and include the identity, pathogenicity, virulence, toxin production, and production of and resistance to antimicrobials. The requirements cover the main hazards related to exposure to microorganisms: infection, intoxication, irritation, hypersensitivity and the development of allergy, and the contribution to antimicrobial resistance. When assessing the safety of microorganisms in microbial cleaning products, the methods for safety assessment already in use in those regulatory frameworks can be used as a basis.

One way to ensure safety assessment of microbial cleaning products could be trying to bring products within the scope of the Biocidal Products Regulation. Another option could be to create a new regulatory framework for microbial cleaning products.

In conclusion, the product group of microbial cleaning products is very diverse, and information on the products is often incomplete. It is often unclear which regulatory framework applies and the commonly applied frameworks for detergents and cosmetics do not include any requirements on the safety of added microorganisms. The most relevant risks for the *Bacillus* species found in microbial cleaning products are irritation after exposure to eyes, skin or via inhalation and the development of contact allergy after exposure via skin or via inhalation.

1 Introduction

Cleaning usually means the removal of dirt or stains and/or the removal of unpleasant odours. This is often done with chemical cleaners containing surfactants. As an alternative for chemical cleaning products, microbial cleaning products containing microorganisms are used in order to remove dirt, stains and/or unwanted odours. In general, the working mechanism of the microorganisms may be via production of enzymes that can break down stains, dirt and odours, or via competition with unwanted microorganisms.

Microbial cleaning products are in this report defined as products meant for cleaning purposes that contain microorganisms in order to perform or facilitate the cleaning process. The term 'microbial cleaning products' is considered in a broad manner, it may include not only household cleaners but also cleaning products for body and hair (personal care products, animal care products) or cleaning products for instruments and tools, such as sport gear, waterbed and air conditioners. Cleaning products containing enzymes but not microorganisms are not taken into account in this project.

This project was executed upon a request by the Office for Risk Assessment & Research of the Netherlands Food and Consumer Product Safety Authority (NVWA-BuRO) and the project aimed at providing:

- an overview of the product group of microbial cleaning products (chapter 2);
- an overview of regulatory frameworks which could apply to microbial cleaning products (chapter 3);
- an overview of the potential risks of the use of microbial cleaning products (risk model given in chapter 4); and
- an inventory of the information needed in order to perform a safety assessment for a microbial cleaning product (chapter 5).

In the overview of the product group, information about working mechanisms and marketing claims available on advertising websites was taken into account. Verifying (the evidence behind) the marketing claims and examining the effectivity of the products was considered beyond the scope of this project.

As the main difference between microbial cleaning products and regular cleaning products is the presence of one or more microorganisms intended to facilitate the cleaning process, the focus of the project is on the microorganisms. Enzymes produced by the microorganisms are not further taken into account. Some attention is given to the preservatives in microbial cleaning products; the chemical ingredients of microbial cleaning products are not further assessed.

2 Microbial cleaning products: an overview of the product group

In order to get a good impression of the product group of microbial cleaning products, a search for microbial cleaning products available on the Dutch market was performed. This search was performed mostly online (in web shops, see Annex 1 for the search strategy), but information was also retrieved from different meetings of the Dutch 'Biocidenoverleg Statusbepaling' (BOS)¹ and a report published by the Netherlands Food and Consumer Product Safety Authority (Nederlandse Voedsel- en Warenautoriteit; NVWA) (NVWA, 2020). The aim of the search was to give a general overview of the product group, including the different types of microbial cleaning products, rather than a complete list of all products available on the Dutch market.

All products containing microorganisms meant for the removal of dirt, stains or unwanted odours were included. In total, 92 microbial cleaning products were found of which 47 were found through the online search, 34 products were retrieved from the report by the NVWA (NVWA, 2020) and 11 products were found in documentation of the BOS-meetings. For each microbial cleaning product, details about the intended use, application form, advertised claims, microorganism(s) present and chemical composition were recorded (see Annex 2).

The information available on the advertising website was found to be limited for a large number of products. In some cases, additional information was found on other websites or web shops advertising the same microbial cleaning product or in safety data sheets. The available information was deemed to provide a sufficient overview of the product group. Nearly all microbial cleaning products found have in common that microorganisms are applied for cleaning purposes, which may be either the removal of dirt and stains or the removal of unpleasant odours. All products were liquids that, for the majority of products, were concentrated and had to be diluted before use. Other liquid products were ready-to-use and a number of liquid products had to be applied as spray.

In addition to the microbial cleaning products, six personal care products marketed for health improving purposes, rather than cleaning purposes were found. Examples of these were a skin cream, a facial spray and a body lotion. These products do not fall within the scope of this project. However, since other microbial personal care products with cleaning purposes have been found, it was decided to include all microbial personal care products in Annex II regardless of their function. Also, it is important to note that there are cleaning products with enzymes on the market, which are of interest due to their possible sensitisation effects.

¹The 'Biocidenoverleg Statusbepaling' is a reoccurring meeting (4 times annually) in which products are discussed that are on the border of being defined as biocide. The organisations taking part in these meetings are the NVWA, RIVM, Dutch Board for the Authorisation of Plant Protection Products and Biocides, Human Environment and Transport Inspectorate, the Ministry of Infrastructure and Water Management, the Health and Youth Care Inspectorate and the Medicines Evaluation Board.

However, since these do not contain microorganisms, they were considered not to fall within the scope of this project and were not included in the report.

2.1 Product group

The products found could be divided into a number of product groups (Table 2-1). Many of the products found were household cleaners, intended for cleaning floors, toilets, sportswear, laundry, drains, interior and containers, or a combination of these when sold as all-purpose cleaners. Secondly, a number of personal care products was found, such as deodorant, shower cream and toothbrush and denture cleaners. Also, microbial cleaning products for animal housing were identified, including stable cleaning products and products for the removal of odours and stains. The search also revealed microbial cleaning products meant for animal care including mostly products for pets, such as animal shampoo, a dental care product for dogs and odour removing products intended to use on animals. In addition, a few garden products were found, being cleaners for artificial grass and a water cleaning product for garden ponds. Last, a number of other products were found including varying types of products such as a cleaning spray for face masks, air conditioner cleaning products, a waterbed conditioner and drain unblocking products.

Table 2-1 Overview of the number of products found for the different product groups, the number of products with information available about the microorganism and the number of products with information about the chemical composition. Products found in the report of the NVWA (NVWA, 2020) and documentation of BOS-meetings are also included in this overview.

Product type	Number of products found	Number of products microorganism specified*	Number of products chemical composition specified
Household cleaners	38	14	Fully specified: 5 Partly specified: 3
Personal care products	17	16	14
Animal housing products	14	6	6
Animal care products	8	4	6
Garden products	3	0	0
Other products	12	5	Partly specified: 3

*This includes the products with *Bacillus* ferment, although the presence of *Bacillus* in these products is unsure (see explanation below).

2.2 Microorganisms in microbial cleaning products

All microbial cleaning products found in the market analysis contained bacteria; products containing other microorganisms (such as phages, yeasts or moulds) were not found. The species was, however, often not provided on advertising websites (see Annex I for details of the search strategy). As this research mainly looked at advertising websites, the species may be declared for example at the label or packaging of the product itself. For detergents, the complete list of ingredients should be available for consumers. If this list is not present at the advertising website, it may be available somewhere else. All products for which the identity of the bacteria was known, contained bacteria from the *Bacillus* genus. Sometimes the *Bacillus* species was known, sometimes it was only identified as '*Bacillus ferment*'² and the species was not given in the product information. For many products, the identity of the bacteria was not given at all. NVWA analysed some microbial cleaning products and identified the *Bacillus* species present in the product (NVWA, 2020). A more detailed description of the available information about the microorganism of the different product types found is given below and in Table 2-2.

2.2.1 *Bacillus*

Bacillus is a genus of Gram-positive³ bacteria consisting of many different species. *Bacillus* species are ubiquitous in nature and are present in for example soil. *Bacillus* species are able to form spores, for example when nutrients are lacking. The spores enable the *Bacillus* species to survive unfavourable conditions, especially as most spores are resistant to heat, cold, radiation, desiccation, and disinfectants. For most microbial cleaning products found, it is not clear whether they contain *Bacillus* as living bacteria or as spores, or a combination.

Two members of the *Bacillus* genus are toxigenic and pathogenic to humans: *Bacillus cereus* and *Bacillus anthracis*.

Bacillus cereus may cause food poisoning via two types of toxins: cereulide and enterotoxins. Cereulide may cause nausea and vomiting; enterotoxins may cause diarrhoea (Stenfors Arnesen et al., 2008). In one microbial cleaning product, a sanitary cleaner, *Bacillus cereus* was observed (NVWA, 2020).

Bacillus anthracis may cause the infectious disease anthrax. It is considered a zoonotic disease as it spreads from animals to humans (Ehling-Schulz et al., 2019). *B. anthracis* was not observed in the microbial cleaning products found.

Other *Bacillus* species are not pathogenic to humans, but may potentially be irritating and/or sensitising. Repeated exposure to sensitising species may lead to the development of contact allergy.

Bacillus species may be used as plant protection product (*Bacillus thuringiensis*), as biocide (*Bacillus amyloliquefaciens*) or in the production of starch or protein degrading enzymes (e.g. *Bacillus subtilis*). Some *Bacillus* species received the Qualified Presumption of

² *Bacillus ferment* is the INCI (International Nomenclature Cosmetic Ingredient) name for the product obtained by the fermentation of *Bacillus*. The INCI name does not specify the species of *Bacillus*.

³ Gram-positive bacteria differ from Gram-negative bacteria in the structure of the cell wall. Gram-negative and Gram-positive bacteria differ in the susceptibility of their cell wall, for example to preservatives.

Safe (QPS) status with the requirement '*absence of toxigenic activity*' (EFSA, 2020b); this means that they can be used safely in food if it is proven that the species does not produce toxins.

In total, eight *Bacillus* species were found: *Bacillus subtilis*, *Bacillus amyloliquefaciens subsp. plantarum*, *Bacillus licheniformis*, *Bacillus mojavensis*, *Bacillus altitudis*, *Bacillus cereus*, *Bacillus megaterium* and *Bacillus pumilus*. In addition, products were found to contain '*Bacillus ferment*'. *Bacillus ferment* is an INCI (international nomenclature of cosmetic ingredients) name for '*the product obtained by the fermentation of Bacillus*' and is found mainly for personal care products. The term '*Bacillus ferment*' does not indicate whether the *Bacillus* is present in the fermentation product and also does not indicate what species. As the microbial cleaning products found were all advertised as microbial or probiotic, it can be expected that *Bacillus* is present, either as living bacteria or as spores.

Examples of *Bacillus* species found in household cleaners were *Bacillus mojavensis* and *Bacillus subtilis* in a product meant for cleaning sports gear and *Bacillus licheniformis* and *Bacillus subtilis* in a dish soap. For some household cleaners, however, '*Bacillus ferment*' was mentioned; this was for example the case for a product intended for cleaning clothes and a home spray intended to reduce odours.

Examples of *Bacillus* species found in personal care products were *Bacillus subtilis* in a toothbrush cleaner, and *Bacillus licheniformis* and *Bacillus subtilis* in a bath foam. For many products, including a shower gel and a deodorant, *Bacillus ferment* was mentioned.

Concerning products for animal housing, microorganisms found were *Bacillus amyloliquefaciens subsp. plantarum* and *Bacillus subtilis* in a cleaning product to reduce urine odour and stains, and *Bacillus subtilis* in a cleaning foam.

The information about the microorganisms in animal care products was limited to four products containing *Bacillus ferment*. Examples were an animal shampoo and a so called '*allergen spray*' product.

For the garden products no information was available about the microorganisms claimed to be present in the products.

Concerning the other products that were found, one air conditioner cleaner and an antifungal product contained *Bacillus* (exact species unknown). More information was available for a cleaning product for sewage and septic tanks and a drain unblocking product, where the first contained *Bacillus subtilis* and *Bacillus pumilus* and the latter contained *Bacillus licheniformis*.

An overview of the different microorganisms found in the different product groups is given in Table 2-2.

Table 2-2 Microorganisms found in the product group by information from the online search, product analysis by the NVWA (NVWA, 2020) and information from BOS-documentation.

Product	Online search	Analysis NVWA	Documentation BOS-meetings
Household cleaners	<i>B. Subtilis</i> * <i>B. Licheniformis</i> * <i>B. Megaterium</i> * <i>B. Amyloliquefaciens</i> * <i>B. ferment</i>	<i>B. subtilis</i> <i>B. amyloliquefaciens</i> <i>subsp. plantarum</i> <i>B. licheniformis</i> <i>B. mojavensis</i> <i>B. altitudis</i> <i>B. cereus</i> <i>B. megaterium</i>	No information available
Personal care products	<i>Bacillus ferment</i>	<i>B. subtilis</i> , <i>B. amyloliquefaciens</i> <i>B. licheniformis</i>	No products found
Animal housing products	No information available	<i>B. subtilis</i> <i>B. amyloliquefaciens</i> <i>subsp. plantarum</i> <i>B. licheniformis</i>	<i>B. amyloliquefaciens</i> ** <i>B. subtilis</i> ** <i>B. licheniformis</i> ** <i>B. pumilus</i> **
Animal care products	<i>Bacillus ferment</i>	No products included	No information available
Garden products	No information available	No products included	No information available
Other products	<i>Bacillus ferment</i>	<i>B. subtilis</i> <i>B. pumilus</i> <i>B. licheniformis</i>	<i>Bacillus ferment</i>

*found in one product included in the online search.

** found in one product included in the documentation of the BOS-meetings.

The *Bacillus* species found may cause irritation reactions when exposure via eyes, skin or inhalation occurs. They may also lead to the development of contact allergy after repeated exposure via skin or via inhalation. One product contained *Bacillus cereus*, a pathogenic species that may produce intoxication after oral exposure.

2.3 Chemical composition of microbial cleaning products

The complete (chemical) composition of microbial cleaning products is regularly not given on the advertising websites, with the exception for personal care products (see Table 2-1). As the products were not acquired, it is not known whether information on the chemical composition was provided on the label or packaging.

For many household cleaners, information on the chemical composition was lacking or incomplete. For the other products, information on the composition was generally given based on the labelling requirements for detergents (as laid down in the Regulation on Detergents, see chapter 3). Those products generally contained surfactants, perfumes and preservatives (such as methylisothiazolinone, MIT).

For personal care products, the information on the chemical composition was found for nearly all products. Most of the products contained water, *Bacillus ferment*, perfume and preservatives. At first sight, the chemical composition of the microbial personal care products seems quite similar to the composition of regular personal care products. The main

difference between regular and microbial personal care products seems to be the presence of the microorganism.

For a number of microbial cleaning products for animal housing the chemical composition was given on the advertising website. Those products contained (besides the microorganism) surfactants, perfume and preservatives. Two household cleaning products and one animal housing product also contained enzymes of which it was unclear whether these were produced by the microorganism or had been added separately.

Concerning animal care products, most of the products found were provided with information on the chemical composition. Products contained surfactants, perfumes and preservatives. In contrast, no information on the chemical composition was available for the garden products.

Among other products that were found, only a product for cleaning wastewater, containing surfactants, and a cleaner for air conditioners, containing ethanol and perfumes, had information on the chemical composition.

2.3.1 *Preservatives*

Preservatives are meant to kill microorganisms or to prevent their growth. The presence and functionality of these substances in microbial cleaning products are discussed in chapter 6.

Throughout the different types of microbial cleaning products a number of preservatives were identified including MIT, benzisothiazolinone (BIT), phenoxyethanol, isopropyl alcohol, alcohol and bronopol. In general, information about the concentrations of preservatives present in products was not available.

For some products, no preservatives were mentioned in the ingredient list. It is unknown whether those products do not contain any preservatives or whether they are not listed.

In the Regulation on Cosmetics (see chapter 3), a positive list of allowed preservatives is established. Preservatives other than those on the positive list are not allowed to be present in cosmetics. In the microbial personal care products, three preservatives were found: MIT, phenoxyethanol and benzyl alcohol. These three preservatives are on the positive list. No microbial personal care products were discovered with unlisted preservatives.

Also, two personal care products did not list any preservatives. Those products, a microbial deodorant and a microbial hand gel, contained denaturated alcohol and isopropanol as solvents and therefore preservatives may not be necessary to prevent decay of the product.

If the Regulation on Cosmetics does not apply, active substances used as preservatives in products '*other than foodstuffs, feeding stuffs, cosmetics or medicinal products or medical devices*' are subject to the Biocidal Products Regulation (BPR, Annex V; see chapter 3 for more details). According to the BPR, cleaning products containing preservatives are '*treated articles*' (see chapter 3). The active substances used as preservatives must be approved, listed in Annex I of the BPR or listed in the review programme of the BPR for the product

type (PT) in which they are used. In this case the product type for used preservatives will be PT6: preservatives for products during storage. We checked the preservatives found. MIT, BIT, phenoxyethanol, isopropyl alcohol, alcohol (as the trade name under REACH for ethanol) and benzyl alcohol are allowed as preservatives for PT6.

2.4 Marketing claims

Often, products were found to be marketed as natural, free from chemicals and environmentally friendly. In addition, many products were advertised as being safe for human and animal health and sometimes as improving health and hygiene. Many microbial cleaning products had claims stating an effective removal of dirt, stains, and/or elimination of unpleasant odours. The underlying mechanism by which this occurs was often claimed to be the introduction of 'healthy' microorganisms which replace hazardous microorganisms by outcompeting them and/or produce enzymes that 'feed' on dirt. Many product descriptions as well as product names contained the term 'probiotic', used for living microorganisms intended to have beneficial health effects. Microbial cleaning products were often advertised as a 'biological' alternative to conventional cleaning products. Also products are frequently claimed to have a fast, thorough and long-lasting effect. A single pet care product was claimed to have allergy preventing effects. For nearly all products, these claims about lack of toxicity, high effectiveness, and cleaning mechanism were made without displaying information supporting these claims. The wording of claims may determine which legal framework is applicable.

3 Regulatory frameworks

In this chapter, an overview is given of existing regulatory frameworks⁴ within the European Union relevant for microbial cleaning products. It is indicated per framework under which conditions a microbial cleaning product may fall within the scope of this framework. Requirements for the product, which are important for enforcement, are determined by the respective frameworks.

If none of the regulatory frameworks described below is applicable, the product falls within the scope of the General Products Safety Directive (GPSD) and the Commodities Act on national level. If so, there are only general rules for the safety of the product. The producer should assess the risks of the products, distributors have to gather and pass on information and retailers have to inform their suppliers immediately if there are complaints or notifications of unsafe situations.

3.1 Detergents

Detergents should comply to the Regulation on Detergents: Regulation (EC) No 648/2004 (EC, 2004). In this regulation, detergents are defined as *'any substance or mixture containing soaps and/or other surfactants intended for washing and cleaning processes'*. The definition does not explicitly include nor exclude products containing microorganisms for cleaning purposes. This means that cleaning products containing microorganisms as well as surfactants may fall within the scope of the Regulation on Detergents.

The Regulation on Detergents contains requirements on the ultimate aerobic biodegradation of surfactants in detergents. Surfactants that do not meet those requirements, cannot be used in detergents unless a derogation is granted by the European Commission.

In addition, the regulation on detergents also sets requirements on the information present on the label of the detergent. This should include:

- the name of the product;
- contact details of the party placing the product on the market;
- information on the content and the ingredients;
- instructions for use and special precautions, if required;
- in case of laundry detergents and consumer automatic dishwasher detergents: dosing instructions.

For the list of ingredients, some ingredients may be given in weight classes (less than 5%; 5 – 15%, 15 - 30%; 30% or more). This holds for soap, surfactants, phosphates, phosphonates and bleaching agents. Some other ingredients – including perfumes, enzymes, optical brighteners and preservatives – should be mentioned on the label regardless of the amount present in the product. Allergenic fragrances should be mentioned as individual substances if added in concentrations

⁴Chemical substances in microbial cleaning products fall within the scope of REACH. As this chapter gives an overview of products instead of chemical substances, REACH legislation is not included.

exceeding 0.01%. Preservatives should be mentioned irrespective of the concentration in the product.

Besides this more general information on the composition of the product, the label should also mention a website where the complete chemical composition of the detergent is available.

The regulation on detergents does not provide any requirements on microorganisms present in the detergents, except that microorganisms should be mentioned in the complete ingredient list.

3.2 Cosmetic products

Some cosmetic products have cleaning properties; they remove dirt (such as shampoo, shower gel, make-up remover) or unwanted odours (such as deodorant). If such product contains microorganisms for cleaning purposes, the product may be seen as a microbial cleaning product.

Cosmetics should comply to the Regulation on Cosmetic products (Regulation (EC) No 1223/2009; EC, 2009a). The rules and requirements in this regulation are established *'in order to ensure the functioning of the internal market and a high level of protection of human health'*.

According to the Regulation on Cosmetic products, a cosmetic product is *'any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours'*. This means that microbial cleaning products meant for use on external parts of the human body may fall within the scope of Regulation (EC) No 1223/2009. Examples include microbial deodorant, microbial shampoo and microbial bath foam.

In general, no authorisation is required for cosmetic products, only a notification. This means that, before the cosmetic product may be placed on the market, the responsible person has to notify the European Commission and provide information on the product. The provided information should include contact details of the manufacturer/distributor, in which member states the product is on the market, information on the composition of the cosmetic product and information on the label and packaging of the product. The provided information also should include a cosmetic product safety report. The European Commission (EC) makes the information available to competent authorities (for market surveillance, market analysis, evaluation and consumer information) and poison centres (for purposes of medical treatment).

In addition to the information requirements, the regulation on cosmetic products also contains requirements on the substances in the cosmetic product. In general, there is a list of prohibited substances which cannot be used in cosmetic products (annex II of the Directive on Cosmetics)

and a list of restricted substances which can be used under specific conditions (for example restrictions in concentration in the product, annex III of the Directive on Cosmetics).

For colorants, preservatives and UV-filters, there is a positive list (annex IV, V and IV of the Directive on Cosmetics). Only colorants, preservatives and UV-filters on the positive list can be used in cosmetic products.

Further, the Regulation on Cosmetic products lays down requirements on the consumer information on the label. The label should contain the following information:

- the name of the product and its function;
- contact details of the responsible person;
- information on the nominal content;
- information on the shelf life and shelf life after opening;
- batch number;
- list of ingredients.

The Regulation on Cosmetic Products does not provide any requirements on microorganisms present in the cosmetic products, except that microorganisms should be mentioned in the ingredient list. It does, however, require that products on the market should be safe under normal conditions of use.

The Implementing Decision (2013/674/EU; EC, 2013) states that the cosmetic product safety report must contain information on the microbiological quality of the product (EC, 2013a). For most products, a preservation challenge test and microbiological quality tests are necessary. For the microbiological limits, the Implementing Decision refers to the SCCS (Scientific Committee on Consumer Safety) Notes of Guidance.

Microbiological limits for cosmetics are given in the 9th revision of the SCCS Notes of Guidance (SCCS, 2016): the total Aerobic Mesophilic Microorganisms (Bacteria plus yeast and mould) may not be higher than 1×10^3 CFU per g or ml. For products intended for children under 3 years of age, for use in the eye area or on mucous membranes, the total Aerobic Mesophilic Microorganisms may not be higher than 1×10^2 CFU per g or ml.

The microbiological limits prescribed in the 9th revision seem not compatible with the use of microorganisms as cleaning agent in personal care products. Recently, NVWA analysed two personal care products: a bath foam and a skin spray (NVWA, 2020). Both products contained microorganisms in amounts much higher than the prescribed limits. Microbiological limits are, however, not included in the current 10th revision (SCCS, 2018). This could be interpreted as meaning that no general specifications for microbial quality apply and that the producer of a cosmetic product may set specifications for microbiological quality for the product.

3.3 Biocides

'Biocidal products' should comply to the Biocidal Products Regulation (BPR) (Regulation (EC) No 528/2012; EC, 2012). This regulation concerns the placing on the market and use of biocidal products

intended to protect humans, animals, materials or articles against harmful organisms by the action of active substances contained in the biocidal product. The purpose of the BPR is to improve the free movement of biocidal products within the EU through harmonisation of the rules, while ensuring a high level of protection of both human and animal health and the environment.

According to the BPR, active substances must be approved by the European Commission for the type of biocidal products (product type, PT) in which they will be used. Biocidal products containing those active substances must be authorised by national competent authorities or by the European Chemical Agency (ECHA) before they can be placed on the market. *'Active substances'* (in a biocidal product) are defined as *'a substance or microorganism with an action on or against harmful organisms'* (BPR, art. 3, 1c). Microbial cleaning products may fall within the scope of the BPR if the microorganisms are active against harmful microorganisms. There is specific guidance for microorganisms used as *'active substances'* to assess the efficacy against harmful organisms and the risks for humans, animals and the environment (see chapter 5 for more information).

Annex V of the BPR describes the product types that fall within the scope of this regulation. Potentially relevant groups for microbial cleaning products are disinfectants (main group 1) and preservatives (main group 2).

Main group 1 is divided into five product types: disinfectants for human hygiene (PT1), disinfectants and algaecides not intended for direct application to humans or animals (PT2), disinfectants for veterinary hygiene (PT3), disinfectants for the food and feed area (PT4) and disinfectants for drinking water (PT5).

Main group 2 are the preservatives. This main group is divided into eight product types, for the preservation of all kind of products. A relevant product type in group 2 may be preservatives for products during storage (PT6).

For microbial cleaning products PT1 to PT4 seem to be the most relevant ones. If microbial cleaning products fall within the scope of the BPR, examples of these biocidal products would be a shower cream falling under PT1, household cleaners falling under PT2 and/or PT4 and a stable cleaning product falling under PT3. A waterbed conditioner might fall under PT6.

The BPR does not only set rules for *'biocidal products'*, but also for so called *'treated articles'*. A treated article means *'any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products'* (BPR art.3, 1l). A microbial cleaning product containing a preservative is a treated article.

The biocidal active substance used in treated articles must be approved, listed in Annex I of the BPR or listed in the review programme of the BPR for the product type (PT) in which it is used.

Besides the BPR states in article 3.1a: *'A treated article that has a primary biocidal function shall be considered a biocidal product'*. For example: a cleaner containing a preservative to protect the product against decay is a treated article; a cleaner containing an active

substance killing, fighting or destroying fungi on the cleaned bathroom wall is a biocidal product.

3.4 Occupational health and safety

In the Directive on the protection of workers from risks related to exposure to biological agents at work (Directive 2000/54/EC; EC, 2000), biological agents⁵ are classified in four risk groups based on the risk of infection:

- Group 1 biological agents are *'unlikely to cause human disease'*;
- Group 2 biological agents can *'cause human disease and might be a hazard to workers; it is unlikely to spread to the community; there is usually effective prophylaxis or treatment available'*;
- Group 3 biological agents can *'cause severe human disease and present a serious hazard to workers; it may present a risk of spreading to the community, but there is usually effective prophylaxis or treatment available'*;
- Group 4 biological agents cause *'severe human disease and is a serious hazard to workers; it may present a high risk of spreading to the community; there is usually no effective prophylaxis or treatment available'*.

Annex III of the Directive gives a list of all biological agents classified as group 1, 2, 3 or 4. This list only contains agents known to infect humans. The list is based on the risk of infection, but also provides information on toxicogenicity and allergenicity of the biological agent where appropriate.

The *Bacillus* species found in the microbial cleaning products are not included in Annex III of Directive 2000/54/EC.

If a microorganism is present in the list in Annex III, this means that the microorganism is an (opportunistic) pathogen; if such microorganism is present in a microbial cleaning product, safety issues may occur. On the other hand, if a microorganism is not listed in Annex III, it does not automatically mean that there are no safety issues. According to the directive, biological agents which have not been classified for inclusion in groups 2, 3 or 4 of the list are not implicitly classified in group 1. In other words, the fact that the *Bacillus* species found in microbial cleaning products are absent in annex III does not mean that they do not pose any health risks for workers.

In addition to the classification of biological agents, Directive 2000/54/EC sets rules and obligations on preventive and protective measures and information required for workers in order to work safely with the biological agents. Employers should keep lists of persons working with each biological agent and should also keep a list of exposed workers in case of accidents and incidents.

3.5 Microbial cleaning products: which framework applies?

It is important to know which regulatory framework applies for a specific microbial cleaning product, because this determines which (legal) conditions the product must meet. Especially if the BPR applies, the

⁵ Including bacteria, fungi, viruses, parasites and cell cultures

producer/distributor is obliged to provide data to show that his product is safe and effective, within the authorisation procedure. The BPR states that this regulation does not apply if the product falls within the scope of the Regulation on Cosmetic products (art. 2.2j BPR). This means that a product can be a cosmetic product or a biocidal product, but not both. This principle applies for products with one primary function. The BPR states in article 2.2k: *'Notwithstanding the first subparagraph, when a biocidal product falls within the scope of one of the abovementioned instruments and is intended to be used for purposes not covered by those instruments, this Regulation shall also apply to that biocidal product insofar as those purposes are not addressed by those instruments'*. This principle applies for products with two different functions. European Guidance (EC, 2013d) states that a product can be a cosmetic product as well as a biocidal product, if the biocidal function (such as insect repellent) and cosmetic function (such as sunscreen) are equally important. It is unclear whether the case law will follow this guidance.

The BPR does not exclude the Regulation on Detergents. This means that a product can be a detergent or a biocidal product or both. For example, a microbial cleaning product containing a surfactant is a detergent. If it also has a biocidal claim, it is a detergent as well as a biocidal product. The Regulation on Detergents then applies alongside the BPR. If there is no biocidal claim, the product is a detergent only falling under the scope of the Regulation on Detergents.

As explained above (paragraph 3.3) microbial cleaning products active against harmful microorganisms may fall within the group of the disinfectants of the BPR. Annex V of the BPR states on disinfectants: *'These product-types exclude cleaning products that are not intended to have a biocidal effect, including washing liquids, powders and similar products.'*

The legal meaning of the word 'biocidal' is discussed below. For the implementation of the BPR, the biocidal claim is important to decide whether or not a product is a biocidal product falling within the scope of the BPR. This is also explained below.

To determine which framework(s) applies for a specific microbial cleaning product the following questions should be answered:

- for products that could fall within the scope of the Regulation on Cosmetic products: is the primary function of the product biocidal or cosmetic?
- for other products: is the product intending to have a biocidal effect or not?

Both questions are discussed below. If the product is not a cosmetic nor a biocide, it can be a detergent without a biocidal effect if it contains soaps and/or other surfactants. If none of these frameworks applies, the product will fall under the generic Commodities Act. Figure 3-1 shows a way to indicatively assess the applicable regulatory framework for microbial cleaning products. For cosmetics, primary and secondary biocidal claims are distinguished (see paragraph 3.5.1 for more explanation).

Currently, the borderline between cosmetics and biocides is under discussion for hydroalcoholic hand gels and differs between different EU-member states. The EC published guidance on this issue (EC, 2020), but the discussion is not finished yet. There is still discussion on which words, phrases, signs or pictures might be or must be seen as a biocidal claim.

Furthermore, it is not clear how to decide on products if there is no biocidal claim at all. It can be stated that if the proposed use of the product makes clear that it must be biocidal and it contains biocidal active substances, the product can be seen as a biocide. How to decide on products with a similar composition but with or without a biocidal claim is discussed in the meetings of the Competent Authorities on biocides in Brussels. Guidance about this issue is, as far as we know, not available yet.

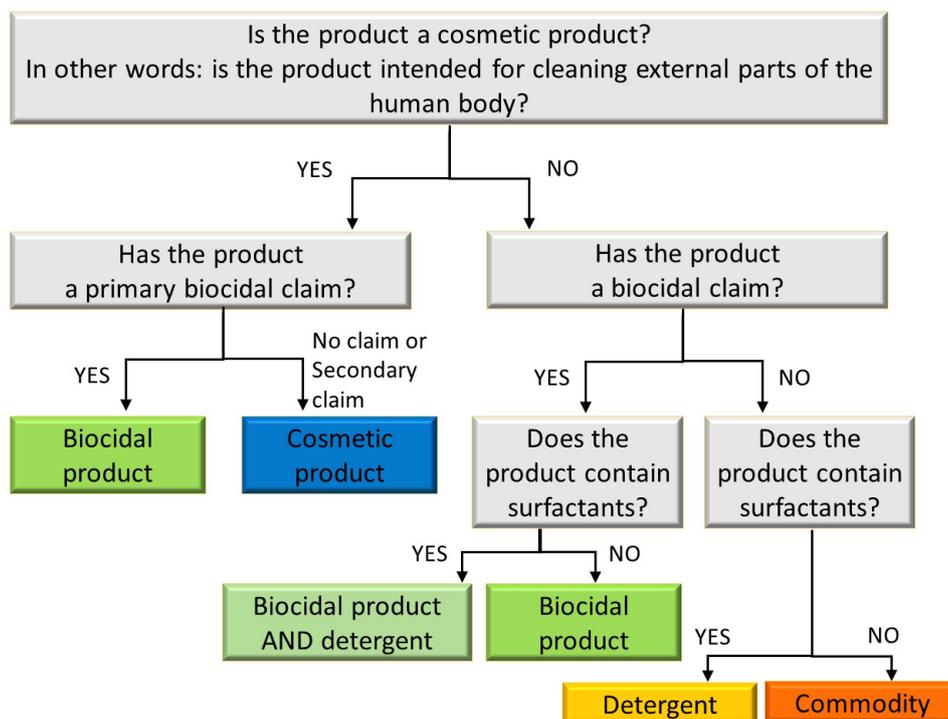


Figure 3-1 Flowchart to indicatively assess whether a microbial cleaning product is a cosmetic product, a biocidal product and/or a detergent or a commodity.

3.5.1

Biocide or cosmetic?

The NVWA uses its own guidance to determine if a product for human hygiene is a medicine, a cosmetic, a medical device, a biocide or a commodity (NVWA, 2009). In the decision whether a product is a biocide or not, the claims that a producer puts on the product and the way the product is marketed (e.g. information given on advertising websites) are crucial. Products with a **primary biocidal** claim are classified as biocides. The guidance states that primary biocidal claims 'are "hard" biocidal claims, where the objective is to kill, destroy, fight, eliminate, completely inhibit the growth of or stop the reproduction of microorganisms (e.g., bacteria). Any product claiming to kill the bacteria

present, render them harmless, or prevent negative effects must be notified as a biocide. Other claims are evaluated on a case-by-case basis to judge whether or not they should be identified as primary biocidal claims. As a matter of principle, the primary cosmetic function of the product must be clear in these cases.' The guidance of the NVWA is based on the Manual of Decisions of the former Biocidal Products Directive (BPD) but is still used.

According to the guidance of the NVWA, primary biocidal claims are: biocide, disinfectant, disinfecting, disinfecting action, for disinfection, fights bacteria and/or fungi, eliminates harmful bacteria and/or fungi, kills bacteria and/or fungi, antiseptic and decontaminating effect. Besides, the claim 'sanitising' is considered to be a primary biocidal claim by the NVWA (personal communication). Claims that may be regarded as primary biocidal claims are antibacterial, antibacterial action, antimicrobial and antimicrobial action. These claims are unclear and the way in which the product is recommended is decisive. If these claims are preceding the product name or are in the product name, then the claim is regarded as a primary biocidal claim.

According to the NVWA guidance, **secondary biocidal** claims are allowed on cosmetic products. Examples are 'helps to control the growth of microorganisms' and 'a deodorant with antibacterial action that prevents malodour caused by bacteria'. The NVWA-guidance states on secondary claims: *'A cosmetic product that prevents the growth of bacteria present, remains under the scope of cosmetics legislation.'*

Preventing the growth of bacteria is not a primary biocidal claim according to the NVWA in their guidance from 2009. When the NVWA decides to update their guidance, the law case (Darie case) described below might change this.

In 2013 the EC published a 'Note for guidance' on the borderline between the legislation for cosmetics and biocides (EC, 2013d). This guidance states that some products have a primary cosmetic purpose and an equally important biocidal purpose. Then the BPR and the legislation on cosmetics apply both. The mentioned example is an insect or jelly fish repellent sunscreen. Microbial cleaning cosmetics seem not to be part of this category for which both regulations apply. The Note for guidance by the EC gives the same view on secondary biocidal claims as described in the NVWA-guidance from 2009: cosmetics with a primary cosmetic function and a secondary biocidal claim are regulated by the Regulation on Cosmetics and do not fall within the scope of the BPR.

In 2020 the 'Working group on Cosmetic Products' published a manual on the scope of the application of the Regulation on Cosmetics (Working group on Cosmetic Products, 2020). The manual is not a European Commission document, it shall only serve as 'tool' and is a collection of practice for the case-by-case application of union legislation by the member states. One example for the borderline between cosmetics and biocidal products is included in this manual: leave-on products presented as antiseptic or antibacterial. The manual states that such a product can be a biocidal product, a cosmetic product, a medical product

or a medical device. It does not give new information on the borderline between cosmetics and biocides.

Due to the Covid-19-crisis there is discussion in the EU on the borderline between cosmetics and biocides, especially concerning hydroalcoholic hand gels. The EC published some guidance (EC, 2020), but the discussion is not finalised yet. The result might be that secondary biocidal claims are not allowed anymore on these type of products under the Regulation on Cosmetic Products. This could also be considered applicable on microbial cleaning products and could lead to renewed NVWA-guidance on borderlines between cosmetics and biocides.

3.5.2 *Intended biocidal effect or not?*

On the website of the Human Environment and Transport Inspectorate (Inspectie voor Leefomgeving en Transport, ILT), a guidance document is available to determine whether a cleaning product is also a biocidal product or not (ILT, 2017). In this guidance, primary or secondary biocidal claims are not mentioned, only 'biocidal claims'. If the product has a biocidal claim on its label or package, it is considered a biocidal product falling within the scope of the BPR. Some examples of biocidal claims are mentioned in the guidance: disinfectant, fights microorganisms, kills microorganisms, sanitising, antibacterial, antimicrobial, algicide and virucide.

Also, when this kind of claims are used for the marketing of the product, e.g. on websites, these products are considered to be biocides. Finally, when the proposed use of the product makes clear that it must be biocidal and it contains biocidal active substances, the product is seen as a biocide. As explained above, 'active substances' can also be microorganisms.

3.5.3 *Recent legal ruling on a microbial cleaning product*

In 2019, the European Court of Justice judged that a microbial cleaning product is a biocide ('Darie-arrest': CJEU, 2019)⁶, despite the lack of a biocidal claim. The product concerned is a 'probiotic cleaning product' containing *Bacillus* ferment. The producer claimed that the product is not a biocide, because it *'generates enzymes that assimilate and consume all the organic waste on which micro-organisms feed, so that, on the surfaces treated with that product, no biotope favourable to the development of micro-organisms such as fungi can form'*. Before using the product *'the mould must be removed to the point where it is totally eliminated'*. The spray must be used every three to four weeks to ensure that the mould does not recur.

The Court judged that products without direct effect on the harmful organisms for which they are intended but with effects on the creation or maintenance of the habitat of the harmful organisms, are to be classified as biocides. This would mean that products preventing the growth of microorganisms are biocides. According to the Court, the fact

⁶ Some explanation of this arrest (in Dutch) can be found here:

<https://www.biociden.nl/nieuws/oordeel-europese-hof-kan-reikwijdte-biocidenverordening-vergroten> and here:

https://ecer.minbuza.nl/-/eu-hof-verduidelijkt-de-betekenis-van-het-begrip-biocide-?redirect=%2Fecer%2Fnieuws%2F-%2Fasset_publisher%2FjXyUjMvIPMrX%2Fcontent%2F-eu-hof-koninkrijk-nederlands-is-onder-unierecht-verplicht-tot-compensatie-van-gederfde-douane-inkomsten-als-gevolg-van-onjuiste-afgifte-exportcertificaten-op-aruba-en-cura%2525C3%2525A7ao

that the product must be used on a clean surface does not influence the classification of being a biocide. The same applies to the period within the product takes effect.

This legal judgment could broaden the scope of the BPR a lot. The case is now returned to the Dutch 'College van Beroep voor het bedrijfsleven' which has to make a final decision. This ruling can be used by enforcers to broaden the scope of the BPR to microbial cleaning products with the intention to prevent the growth of microorganisms or to control the effects of them (for instance unwanted odours).

3.5.4 *Legal ruling on biocidal products acting indirectly*

In 2012, the European Court of Justice handled a case about an anti-algae product ('Söll-arrest': CJEU, 2012). Although the active substance was not directly destroying or deterring algae, it was still judged to be a biocidal product. The Court wrote: *'In view of the foregoing, the answer to the questions referred is that the concept of 'biocidal products' set out in Article 2(1)(a) of Directive (EU) No 98/8 must be interpreted as including even products which act only by indirect means on the target harmful organisms, so long as they contain one or more active substances provoking a chemical or biological action which forms an integral part of a causal chain, the objective of which is to produce an inhibiting effect in relation to those organisms.'*

This ruling can also be used to broaden the scope of the BPR to microbial cleaning products.

3.6 **Applicable frameworks for the products found**

3.6.1 *Cosmetics*

Products for personal care may fall within the scope of the BPR if they have a primary biocidal claim, such as being a disinfectant or fighting bacteria. If not, they may fall within the scope of the Regulation on Cosmetic products. Within the latter regulation, secondary biocidal claims such as preventing the growth of bacteria or preventing malodour caused by bacteria, are allowed at the moment. As described above, this might change in the future.

Because the requirements for biocidal product under the BPR (approval of active substances and authorisation of products) are more demanding than for cosmetics, producers will most likely prefer secondary biocidal claims. Most of the personal care products we have found will fall within the scope of the Regulation on Cosmetic products at the moment. We did not find any microbial cosmetic cleaning product authorised under the BPR. One product uses the word 'ontsmetten' (antiseptic) in its name which is a primary biocidal claim according to the guidance of the NVWA (NVWA, 2009).

3.6.2 *Non-cosmetics with a clear biocidal claim*

The other (non-cosmetic) microbial cleaning products will fall within the scope of the BPR when there is a biocidal claim. During our search we found three claims that can be assessed as biocidal: *'bestrijding van ongewenste organismen'* (controlling unwanted organisms), *'vernietigen van mos, algen en dagelijks vuil'* (destroying mosses, algae and daily

dirt) and 'ontsmetten' (disinfecting). Products with these claims can be seen as non-authorised biocides. When we looked again at a later stage in this project, the products with the first two claims mentioned here did not have these claims anymore in their advertising text on the website.

At the moment, there is one *Bacillus* species approved as an active substance for a Product Type relevant for microbial cleaning products. This concerns *Bacillus amyloliquefaciens* ISB06 approved for PT3 (veterinary hygiene). The biocidal product assessed in the Assessment Report is 'Cobiotex 112 biofilm +'. It is a product designed to control potentially harmful bacteria in livestock buildings and equipment of animal rearing facilities, e.g. for poultry and pig. The product is intended to complement but not substitute chemical disinfection measures as a prophylactic treatment. The biocidal product is applied by spraying on abiotic surfaces. The Assessment Report is available on the website of ECHA⁷. The evaluating Competent Authority (eCA) for this Assessment Report was Germany.

On the list of active substances for biocidal products is one other *Bacillus* species in PT3. This concerns *Bacillus subtilis*. The status given on the ECHA-website is 'no longer supported'. This means that there are no applicants anymore who will compile and submit a draft assessment report for evaluation by the eCA. The reason why the applicants have withdrawn their support is unknown. The eCA for *Bacillus subtilis* was also Germany.

The finding that one *Bacillus* species is approved in PT3, shows that the BPR can be applicable on microbial cleaning products.

3.6.3 *Non-cosmetics without a biocidal claim*

Most of the claims are rather vague, e.g. introducing healthy microbes, probiotic, hygienic and preventing malodours.

The legal rulings described above show that microbial products acting indirectly on microorganisms may be assessed as products falling within the scope of the BPR. Still, the borderline between being biocidal and 'only cleaning, removing the bacteria' is narrow and under discussion.

Microbial cleaning products may fight bacteria or remove their food environment, which can be judged as biocidal. But these products can also only break down or scavenge the substances causing the malodour or just mask the bad smells with pleasant odours, which can be judged as not biocidal. It will not be easy to know exactly the working mechanism of microbial cleaning products.

There seems to be suitable case law to bring some microbial cleaning products within the scope of the BPR, even if there are no biocidal claims, as they contain microorganisms as an active substance. The guidance on borderline products (ILT, 2017) states that when the proposed use of the product makes clear that it must be a biocidal product and it contains biocidal active substances, the product is seen as a biocide. For many microbial cleaning products, the exact working

⁷ <https://echa.europa.eu/documents/10162/9d91425c-3309-7be3-9253-cc3871821fe6>

mechanism will be unknown, making it difficult to show that the working mechanism is biocidal. The current situation is that these products fall within the scope of the Regulation on Detergents (when they contain a surfactant) or within the scope of the Commodities Act (products without surfactants).

Many of the household cleaners, animal housing cleaners, garden products and other products found on the Dutch market contain both microorganisms and surfactants. Therefore, those products may fall within the scope of the Regulation on Detergents. For other products, including household cleaners without detergents and animal care products, no specific regulatory framework applies. Those products fall within the scope of the Commodities Act.

Except for the BPR, none of the applicable regulatory frameworks includes specific requirements for the microorganisms present in the products. The only requirements are to include the microorganism in the list of ingredients and the general requirement that products on the market should be safe under normal conditions of use. In the 9th revision of the SCCS guidance (SCCS, 2016), limits for microbial quality are prescribed for cosmetic products, although those microbial limits are not included in the current 10th revision.

3.6.4 *Conclusions on applicable frameworks*

At the moment, most microbial cleaning products found in the product search fall within the scope of the Regulation on Detergents, the Regulation on Cosmetic Products or General Product Safety Directive (GPSD) or the Commodities Act. We did not find any microbial cleaning product authorised under the BPR. Yet, approval of microorganisms as active substances under the BPR is possible and there is one approved *Bacillus* species for use in biocidal products for veterinary hygiene. The current discussion on hydroalcoholic hand gels in the European Union could lead to the decision that secondary biocidal claims are not allowed anymore on hand gels under the Regulation on Cosmetic Products. This might lead to the situation that more or even all products with a secondary biocidal claim will fall within the scope of the BPR. Besides, the described court cases could also broaden the scope of the BPR in the future.

4 Potential risks: a risk model

Microorganisms present in microbial cleaning products may pose a risk to humans, animals and the environment. The risk model described in this chapter aims at giving a general overview of potential hazards in microbial cleaning products, as well as an overview of potential routes of exposure relevant for the product group.

In addition to the general overview, attention paid specifically to *Bacillus* (the only genus found in the market analysis) is presented.

The model is relevant for household and professional cleaning products, as well as for care products for humans and animals. The risk model is not meant as a (quantitative) risk assessment method and does not focus on hazards other than those caused by microorganisms.

Microorganisms include bacteria, fungi (including moulds and yeasts), viruses (including phages) and parasites. The application of microorganisms in cleaning products can be harmful if the applied organism has hazardous characteristics and when the genes encoding these characteristics are being expressed at the time of exposure. Each potential risk (either for humans, animals or the environment) linked to the use of such microbial cleaning product is determined by the intrinsic hazard and the level of exposure. Susceptible people (young, old, pregnant or immuno-compromised) maybe at higher risk than the general population.

4.1 Hazards

In order to give an overview of hazards potentially related to microbial cleaning products, it is important to know what microbiological hazards are present and what the potential effects of the microbiological hazards are.

4.1.1 Identification of the hazard

The effects that can be expected after exposure to a microbiological agent depend on the agent and its characteristics. It is therefore important to identify the microorganism present in the microbial cleaning product. Some microbiological agents are not easily identified or distinguished from related species. This is a relevant challenge for *Bacillus* species.

Bacillus species can roughly be divided into two groups: the *B. cereus* group (among which *B. cereus*, *B. anthracis*, *B. mycoides* and *B. thuringiensis*) and the *B. subtilis* group (among which *B. subtilis*, *B. amyloliquefaciens*, *B. licheniformis*, *B. pumilis* and *B. mojavensis*). Within those two groups, it is not easy to distinguish between the different species. This is especially relevant for the *Bacillus cereus* group, as this group includes both pathogenic (*B. cereus* and *B. anthracis*) and non-pathogenic (*B. mycoides* and *B. thuringiensis*) species which are difficult to distinguish (Rooney et al., 2009; Ehling-Schultz et al., 2019).

In addition it is important to realise that contamination with non-identified, unwanted organisms may occur during production, storage and use.

4.1.2 *Effects caused by the microorganism*

Effects of microbiological hazards in humans may be either symptomatic or asymptomatic. Asymptomatically infected persons have no symptoms, but they can spread a microbiological hazard among a population. Symptomatic effects may be local or systemic. Local effects of exposure to a microorganism may include irritation and sensitisation; potential systemic effects may include infections and intoxications.

Exposure to a microorganism can result in an infection and related illness. This depends on the pathogenicity and virulence of the microorganism. Infections may be local (for example infection of the skin or eye) or systemic if the microorganism enters the blood circulation. Bacterial cells of pathogenic *Bacillus* species can infect the host and cause disease. Disease is, however, not the result of the bacterial cell itself, but results from the production of its endotoxin.

Many microorganisms have irritating and sensitising properties or produce proteins (including but not limited to enzymes) with irritating or sensitising properties. Therefore, exposure to microbial cleaning products may cause irritation of the eyes, skin and/or respiratory tract. In addition, exposure to sensitising microorganisms may cause a contact allergy after skin exposure or after inhalation. Validated test methods to test skin sensitisation and respiratory sensitisation are not available. Therefore, microorganisms in general are considered as potentially sensitising unless evidence shows otherwise. This principle is for example practised in the regulatory framework for plant protection products (EC, 2013b) and for biocides (ECHA, 2017).

An infection with any microorganism that produces antibiotics can disturb the normal microbiome and forms a threat for people receiving antibiotic treatment.

Extracellular structures, enzymes and/or other organic compounds that are released in cell-lysis can cause sensitisation.

4.1.3 *Effects caused by toxins or metabolic products*

Microorganisms, including some *Bacillus* species, can also cause an intoxication as some species produce toxins or harmful metabolites, like biogenic amines and alcohol. The production of these toxins can occur in the cleaning product, but also after exposure during an infection.

B. cereus, found in one microbial cleaning product, is toxicogenic. It produces two types of toxins: cereulide (produced in the product) that can cause vomiting or enterotoxin (produced in the intestines during infection) that can cause diarrhoea (Stenfors Arnesen et al., 2008; Ehling-Schultz et al., 2019).

Although not identified in any of the microbial cleaning products, *B. anthracis* must also be mentioned because of its highly virulent nature (Ehling-Schultz et al., 2019).

Production of biogenic amines was reported for *B. licheniformis* and *B. subtilis* (Chang et al., 2011; Lee et al., 2019).

4.1.4 *Spreading of antimicrobial resistance*

Dissemination of genetic information coding for antimicrobial resistance (AMR) can also be considered as hazardous. Some *Bacillus* species, including *B. anthracis*, *B. cereus* and *B. thuringiensis*, have been reported to contain AMR genes and may therefore contribute to the spread of antimicrobial resistance (Lee et al., 2019; Taitt et al., 2020; Zhu et al., 2016).

4.2 **Potential exposure**

In order to give an overview of exposure scenarios that could be relevant for the product group, the following questions are answered:

- Who are (or may be) exposed to the microorganisms in the microbial cleaning products?
- How are they exposed to these microorganisms? What are the (potential) exposure routes?
- To what amount are they possibly exposed?

4.2.1 *Exposure of humans, animals and the environment*

Humans

For microbial cleaning products, the following groups of people may be exposed:

- Producers: the persons working in the production of the microbial cleaning product;
- Users: the persons using the cleaning product. In case of products for professional use the users will generally be trained, but in case of consumer products the user is generally not trained. For products used and stored at the household, children may get access to the product;
- Persons in contact with cleaned items or surfaces. For example, when sports equipment in a gym is cleaned by a (professional) cleaner with a microbial cleaning product, the person using the sports equipment may be exposed to the microbial cleaning product as well. Another example is when public toilets are cleaned by a professional cleaner with a microbial cleaning product and the person using the toilet is exposed;
- In case of a spray, by-standers may also be exposed.

Any person with a higher susceptibility for infectious diseases (Young, Old, Pregnant or Immuno-compromised) is at a higher risk of developing adverse effects after exposure.

In addition to people, also animals and the environment may be exposed to the microbial cleaning products.

Animals

In some cases, animals can be exposed via cleaned surfaces. For example when they eat from a bowl that has been cleaned with a microbial detergent. In other cases, the animals can be exposed more directly, for example in the case of microbial dog shampoo or a microbial cleaner for stables used while livestock is present in the stable.

Exposure of animals via drinking contaminated surface water (see below) is also possible.

Exposure of food-producing animals might also lead to the introduction of microorganisms (from a microbial cleaning product) in the food chain. This especially holds true when the microorganism is able to colonise and multiply in the food-producing animal.

Environment

Microbial cleaners may end up in the environment. Due to rinsing of cleaned surfaces, microorganisms will reach the industrial or domestic waste water system, entering the environment. After use, cleaning products will enter the sewage system if the suds are discarded. If microbial cleaning agents survive the industrial or domestic waste water treatment, they will enter the environment (surface water) where they can possibly multiply and spread if the conditions are suitable.

4.2.2 *Potential exposure routes*

Exposure to microbial cleaning products may occur via several exposure routes, depending on the product and its application. The most relevant routes are:

- Dermal exposure;
- Oral exposure;
- Respiratory exposure.

Dermal exposure (including exposure via eyes and ears) is most likely the main route of exposure for many microbial cleaners. Skin contact may occur during cleaning with a microbial cleaning product (user), such as a floor cleaner or an all-purpose cleaner. Dermal exposure may also occur due to the use of microbial personal care products, such as bath foam, shower gel, shampoo and hand gel.

In addition, skin contact may also occur after cleaning via the cleaned surfaces or items. For example, skin contact may occur via clothes washed with microbial washing detergent or via chairs or table surfaces cleaned with microbial all-purpose cleaner. Children (when playing on the floor) or animals may also be exposed when the floor has been cleaned with a microbial floor cleaner.

For some products found on the Dutch market, such as a microbial toothbrush cleaner and a cleaning spray for face masks, direct oral exposure may occur. For most products, however, direct oral exposure to microbial cleaning products is not very likely for adults, but may occur when young children (or animals) accidentally ingest the product. Oral exposure will mostly occur due to spilling and splashing or due to hand-to-mouth contact. These routes will generally be applicable for the user. Hand-to-mouth contact may also occur after the use of microbial hand gel.

In addition, oral exposure may occur via cleaned items (consumer, animal), for example via cutlery and plates washed with a microbial detergent or when an animal eats or drinks from a bowl that has been cleaned with a microbial cleaner.

Oral exposure may also occur via contaminated food. This may include food from food-producing animals that are housed in stables cleaned

with a microbial cleaning product, and food that contacted surfaces that were cleaned with a microbial cleaning product.

During cleaning, especially when a microbial cleaning product is sprayed, also respiratory exposure may occur. This obviously holds true for the user, but it may also hold true for others (people or animals) present in the room. Especially when the room is not well-ventilated, this exposure may occur for some time after the cleaning event. Examples of microbial products that may be sprayed include cleaning sprays, odour removing sprays and deodorant sprays. In addition to spraying, respiratory exposure may also occur during showering and hair washing or when wearing face masks cleaned with cleaning spray for face masks.

4.2.3 *Exposure levels*

In general terms, the level of exposure of a person to any microbiological agent depends on the frequency and time span of use, the concentration (of microorganism in the cleaning product and of cleaning agent in the final cleaning solution) and on the cleaning procedure. Cleaning procedures that include the use of high pressure have a different risk (mainly respiratory exposure) compared to manual procedures (mainly dermal exposure). The use of personal protection equipment (e.g. gloves and face masks) can reduce the level of exposure.

It is difficult to quantitatively calculate human exposure to microorganisms via microbial cleaning products, as microorganisms may increase or decrease in numbers during production, storage and use. This may even go on after cleaning if the microorganism is present on the cleaned surface.

The level of environmental exposure will depend on the frequency, the concentration (of microorganism in the cleaning product and of cleaning agent in the final cleaning solution) and on survival and multiplication capacities of microorganisms in untreated and treated waste water.

The level of exposure of animals will depend on the residual numbers of microorganisms on a cleaned surface. Or, when drinking contaminated waste water, on the concentration in and frequency and amount of water consumed.

4.3 **Potential risk**

The potential risks posed by microbial cleaning products depend on the hazard (the microorganism present in the product and the effects it may cause in humans, animals and the environment) and on the exposure (exposure route and amounts). If the level of exposure and the hazard are known for a microbial cleaning product, the risk for that specific product can be calculated. This information is often not complete and therefore a quantitative risk assessment is mostly not possible.

This risk model does not aim at calculating quantitative risks for specific products, but aims at giving a general overview of potential risks, based

on the hazards in microbial cleaning products and on the potential routes of exposure relevant for the product group.

In order to illustrate the potential risks related to microorganisms in microbial cleaning products, two products are used as an example.

4.3.1 *Example 1: Sanitary cleaner*

A sanitary cleaning product meant for cleaning toilets and sanitary rooms and preventing unwanted odours was found on the Dutch market. The product is a concentrated cleaner; it should be diluted to 0.5-1% before use. According to the advertising website of the manufacturer, the product contains probiotic bacteria that have the QPS status for use in food.

According to analysis performed by the NVWA (NVWA, 2020), the product contains *Bacillus amyloliquefaciens* spp. *Plantarum*, *Bacillus cereus* and *Bacillus licheniformis*. As *B. cereus* is pathogenic after oral exposure, it does not have the QPS status. It is therefore most likely that the presence of *B. cereus* is unintended and may be the result of contamination or mix-up of *Bacillus* species.

B. amyloliquefaciens spp. *Plantarum* and *B. licheniformis* are granted the QPS status with the requirement 'absence of toxigenic activity'. This indicates that no hazardous effects are expected after oral exposure. *B. cereus* is pathogenic and may lead to illness after oral exposure due to endotoxins it produces.

For all three *Bacillus* species, evidence showing the absence of irritating and sensitising properties is lacking. Therefore, the three *Bacillus* species are considered to have irritating and sensitising potential.

The main exposure route for this product is considered to be the dermal route. Skin exposure may occur during cleaning and via cleaned surfaces. Eye exposure and oral exposure may occur due to splashing or to hand-to-eye and hand-to-mouth contact. Oral exposure may also occur if children accidentally ingest the product. Inhalation of the product seems to be a minor exposure route.

Combining information on the exposure routes and the hazards, it seems that the risk of illness due to the presence of *B. cereus* will be low, as oral exposure is not a main exposure route. There could be a reasonable risk of skin irritation and skin sensitisation with this specific product, especially during cleaning.

4.3.2 *Example 2: Microbial deodorant*

This microbial deodorant is a spray to be applied directly to the skin. According to the advertising website, it fights unwanted odours and works up to 48h. According to the ingredients list, it contains *Bacillus* ferment. This is the INCI name for 'the product obtained by the fermentation of *Bacillus*'. This INCI name does not provide information on the *Bacillus* species.

The *Bacillus* species is not known. Therefore, evidence showing the absence of irritating and sensitising properties is lacking and the product is considered to have irritating and sensitising potential.

If the product contains pathogenic *Bacillus* species, illness may also occur.

As the product is a deodorant spray, the main exposure routes are dermal exposure and inhalation. Eye exposure may accidentally happen, both directly or via hand-to-eye contact. Oral exposure may occur via hand-to-mouth contact.

Combining the information on potential exposure routes and hazards, it seems that using this product may lead to a reasonable risk of irritation of the skin and respiratory tract. In addition, there is a risk of developing contact allergy due to the potential sensitising properties. The potential risk of infection or intoxication depends on the *Bacillus* species present, and cannot be assessed based on the information available.

5 Inventory: requirements for safety assessment

As described in chapter 3, most microbial cleaning products found in the product search may fall within the scope of the Regulation on Detergents, Regulation on Cosmetic Products or within the scope of the Commodities Act. Those frameworks, however, do not provide requirements or guidance on the microorganisms present in the microbial cleaning products.

Some products may fall within the scope of the regulatory framework for biocides, in which requirements for the safety aspects of microorganisms are laid down. In addition, in other regulatory frameworks, information requirements for safety assessment purposes for microorganisms are laid down. Although those other frameworks (mainly those on plant protection products and on food and feed) are not applicable to the microbial cleaning products, the method of assessing the safety of applied microorganisms may be applicable.

The goal of this chapter is to give an inventory of the information needed to perform a safety assessment on microorganisms present in microbial cleaning products. This inventory is based on the requirements in other regulatory frameworks, namely the frameworks for biocides, for plant protection products and for food and feed. First, the frameworks are described and then the relevant information requirements for the safety assessment of microorganisms in microbial cleaning products are selected.

5.1 Biocides

The authorisation of biocidal products requires extended evaluation of the risks linked to its use. First, the active substance has to be approved and subsequently the biocidal product containing the substance has to be authorised (for more information, see chapter 3).

The applicant has to prepare a dossier for approval of the active substance. This dossier is evaluated by a national competent authority. The Biocidal Product Committee of the European Chemicals Agency (ECHA) writes then an opinion for approval or non-approval of the active substance and the European member states make the final decision.

The information requirements for microorganisms as active substances are described in Annex II (under Title 2) of the BPR. Those information requirements are quite specific, but in general terms the following information is required:

- Identity of the microorganism, including the common name, taxonomy and identification method as well as the presence of additives and of chemical and microbiological impurities;
- Biological properties of the microorganism, including the origin, natural occurrence, historical use, relation to pathogens, production of toxins and production of and resistance to antimicrobial agents;
- Methods of detection and identification;
- Effectiveness against target organisms;

- Intended use and exposure;
- Effects on human and animal health, including information on pathogenicity, toxicity, sensitisation, residues and persistence;
- Effects on non-target animals in the environment;
- Environmental fate and behaviour;
- Protection measures; and
- Classification, labelling and packaging.

ECHA wrote a specific guideline for the evaluation of active microorganisms and its biocidal products (ECHA, 2017). This guidance provides technical advice on the information requirements and on the risk assessment. The risk assessment should take into account:

- the hazards due to the biological properties of the microorganism as well as physicochemical properties of the formulation including co-formulants;
- the exposure to humans, animals and to the environment;
- the risk to humans, animals and the environment; and
- the measures necessary to protect humans, animals and the environment from exposure, both during the proposed normal use of the biocidal product and in a realistic worst case situation.

5.2 Plant protection products

The registration of plant protection products (PPP) is controlled in Regulation (EC) No 1107/2009 (EC, 2009b). The purpose of this Regulation is *'to ensure a high level of protection of both human and animal health and the environment and at the same time to safeguard the competitiveness of Community agriculture'*.

Before the combination of a product with a specific use on a crop can be authorised by national competent authorities, the active substance has to be approved in the EU. The rules for approval of the active substance and for the authorisation of plant protection products are laid down in Regulation (EC) No. 1107/2009. The general principles for the evaluation and authorisation of plant protection products are described in Regulation (EU) No. 546/2011 (EC, 2011).

The specific data requirements for active substances are laid down in Regulation (EU) No. 283/2013 (EC, 2013b) and for plant protection products in Regulation (EU) no. 284/2013 (EC, 2013c).

The applicant has to prepare a dossier for approval of the active substance. This dossier is evaluated by a national competent authority. The European Food Safety Authority (EFSA) writes an opinion for approval or non-approval of the active substance and the European member states make the final decision.

In the approval process for active substances, the efficacy in plant protection as well as the absence of unacceptable effects on plants and plant products are evaluated. In addition, the impact of the active substance and its possible residues on human health, animal health and the environment are evaluated. In the evaluation of microbial plant protection products, both the microorganism as well as relevant metabolites, toxins, contaminants and residual growth medium is taken into account.

The information requirements for the approval of a microorganism as an active substance are laid down in Regulation 546/2011 and more detailed in Regulation 283/2013. In general terms, the following information is required for the evaluation and approval:

- Identity of the microorganism;
- Biological properties of the microorganism, including the origin, natural occurrence, mode of action, pathogenicity, virulence, production of and resistance to antimicrobials;
- Quality controls during production of the active substance;
- Efficacy;
- Methods for identification, detection and quantification;
- Impact of the microorganism and residues thereof on human and animal health, including pathogenicity, production of toxins and the ability to persist;
- Fate and behaviour in the environment; and
- Effects on non-target organisms in the environment.

It is stated that sufficient information has to be submitted to evaluate the foreseeable risks for humans, including vulnerable groups, animals and the environment. Several guidance documents are available about the information requirements and on the preparation of dossiers for active substances including microorganisms. For example, a guidance for applicants on preparing dossiers for the approval of a microbial active substance (EC, 2016) is available on the EU website. In addition, the Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) wrote an Evaluation Manual for biopesticides describing the data requirements and risk assessment for biopesticides including microorganisms (Ctgb, 2018).

5.3 Food and Feed

Micro-organisms are widely used in the production of food and feed. They are used to give products the desired taste or texture (cheeses, wine, bread), but they are also used to extend a product's shelf life (e.g. cheese from milk, fermented sausages from raw meat or silage). In food and feed, microorganisms may also be used as active ingredients in probiotics or as production organism in the production of for example enzymes or amino acids. In probiotics, viable microorganisms are present. When used as a production organism, normally the microorganism is not present in the food or feed at the time of consumption.

The safety of microorganisms used in food and feed is assessed by EFSA. In order to provide a harmonised, generic safety evaluation for biological agents intentionally added to food and feed, EFSA developed the Qualified Presumption of Safety (QPS) approach⁸. If a safety assessment performed by EFSA shows that a group of microorganisms does not raise safety concerns, the group is granted the 'QPS status'. For those microorganisms, a full safety assessment is not required as they are presumed to be safe for humans, animals and the environment.

The list of microorganisms granted the QPS status is maintained and re-evaluated approximately every 6 months by EFSA (EFSA, 2020a; EFSA,

⁸ More information see <http://www.efsa.europa.eu/en/topics/topic/qualified-presumption-safety-qps>

2020b). Microorganisms that are not considered (suitable) for QPS status must undergo a full safety assessment.

The safety evaluation of microorganisms as performed in the QPS approach is based on four pillars (EFSA, 2020a):

- The taxonomic grouping or taxonomic identification of the (group of) microorganism(s);
- The amount of knowledge available;
- Safety and safety concerns;
- Intended uses.

Some (groups of) microorganisms are granted the QPS status with qualifications. This may be the case if safety concerns that can be easily excluded at species level, are identified for the microorganism(s). For example if some species may produce toxigenic compounds. If a specific species satisfies the qualifications, no full safety assessment is needed. Species that fail to satisfy the qualifications should undergo a full safety assessment (EFSA, 2017).

The QPS approach is also applicable to genetically modified microorganisms (GMOs) to be used as recipient species. In addition to the QPS criteria, the genetic modification should not give rise to safety concerns (EFSA, 2020a).

The QPS approach does not address specific hazards for users handling the product. This means that a general safety evaluation for humans is performed, based on the exposure routes (mainly ingestion) and exposure levels relevant for consumers. Other exposure routes (for example dermal exposure and inhalation) and exposure levels relevant for users handling the product (for example workers in the food enzyme production plant) are not taken into account specifically.

In addition, the QPS approach does not take into account any hazards linked to the formulation or processing of products containing microbial agents.

EFSA performs a safety assessment for a microorganism once an application dossier is notified to EFSA. The requirements for such an application dossier are listed in several guidance documents for different product types and depend on regulatory requirements. In general the requirements include (EFSA, 2018; EFSA, 2014):

- Taxonomic identity of the species;
- If applicable: information on QPS status and/or history of safe use;
- Procedures for the control and monitoring of the species, including culturing procedures, procedures to ensure pure culture, hygienic procedures and identification methods used;
- Information on production (fermentation) process and purification process;
- Pathogenicity;
- Toxigenicity;
- Production of antibiotics;
- Antimicrobial resistance;

- presence of natural and/or acquired antimicrobial resistance genes;
- antimicrobial susceptibility.

5.4 Relevance for microbial cleaning products

As described in the risk model in chapter 4, microbial cleaning products may pose risks to humans, animals and the environment. Depending on the product and its use, humans and animals may be exposed to the microorganisms in microbial cleaning products via skin contact, ingestion or inhalation. Hazards that may arise from the microorganisms include:

- infection (depending on the pathogenicity and virulence of the microorganism);
- intoxication through toxins produced by the microorganism;
- irritation or allergy if the microorganism has irritating or sensitising properties.

In addition, microorganisms may produce antimicrobials or have resistance against antimicrobials and may contribute to antimicrobial resistance.

As described above, in the regulatory frameworks for food and feed, biocides and plant protection products, microorganisms are included and methods for risk assessment are developed and in use. For all three frameworks, an authorisation is needed before a product can be placed on the market and the applicant has to send in a dossier for risk assessment. The dossier requirements for the authorisation or approval procedure are laid down in legislation and in guidance documents. The dossier requirements for microorganisms are similar in the three regulatory frameworks and cover the identity, pathogenicity, virulence, toxin production, and production of and resistance to antimicrobials. The dossier requirements cover the possibilities of microorganisms to cause infection, intoxication, irritation, allergy as well as their contribution to antimicrobial resistance.

The safety assessment for microorganisms in food and feed (especially within the QPS approach) focusses on exposure via ingestion. As other routes of exposure (dermal exposure, inhalation) may also be relevant for microbial cleaning products, additional properties of the microorganism are relevant when the microorganism is used in microbial cleaning products. Examples are information on irritating properties after skin and eye exposure and sensitising properties after dermal exposure or inhalation. Therefore, microorganisms granted the QPS status for use in food and feed are not by definition safe for use in microbial cleaning products.

For example, most *Bacillus* species are granted the QPS status with the requirement 'absence of toxigenic activity'. This means that these species are considered safe in food and feed if proven that the species do not produce harmful toxins. This, however, does not necessarily mean that these species can also be used safely in microbial cleaning products.

In addition, some *Bacillus* species have been assessed under the regulatory frameworks for biocides and plant protection products.

Bacillus amyloliquefaciens ISB06 has been approved as active substance for biocides in PT3 (veterinary hygiene). Currently, several *Bacillus* species are approved as active substances in plant protection products, including *Bacillus amyloliquefaciens*, *Bacillus pumilus* and *Bacillus subtilis* which are also found to be used in microbial cleaning products. For those *Bacillus* species, an assessment report is available.

If a new separate method to assess the safety of microorganisms in microbial cleaning products is set up, this can be largely based on the safety assessments already in use in the three regulatory frameworks described above. In general, the three frameworks have similar information requirements and similar methods for risk assessment. In those three regulatory frameworks, not only the safety but also the efficacy of the microorganism is evaluated.

6 Discussion and conclusions

6.1 Overview of the product group

The group of microbial cleaning products consists of a wide variety of products. A search for microbial cleaning products available on the Dutch market showed that most of the microbial cleaning products found were household cleaners, followed by personal care products and cleaning products for animal housing.

For most microbial cleaning products found, the information (especially information on the chemical composition and on the microorganism present) available on the advertising websites was limited.

All microbial cleaning products found contain bacteria. Products for which the species was known all contained one or more *Bacillus* species. *Bacillus* is a genus of spore-forming bacteria. For most microbial cleaning products found, it is not clear whether they contain *Bacillus* as living bacteria or as spores, or a combination.

Two *Bacillus* species are pathogenic: *B. anthracis* and *B. cereus*; the latter was found in one microbial cleaning product. Because of the description of this product, the presence of *B. cereus* is most likely to be due to contamination or mix-up of *Bacillus* species during production. This shows that contamination of a microbial cleaning product with unwanted *Bacillus* species could be a serious problem.

6.1.1 Preservatives

Some microbial cleaning products contain preservatives, mainly MIT and phenoxyethanol. Microbial cleaning products containing solvents with preserving properties (such as ethanol and isopropanol) were also found.

Preservatives are added to products to prolong the shelf life of the product and to prevent unwanted microorganisms to deteriorate the product. In microbial cleaning products, preservatives should eliminate unwanted microorganisms without harming the microorganisms added as active substances. Therefore the question rises whether preservatives in a product affect the survival of the intentionally added microorganisms in the product.

As was demonstrated by the product analysis of the NVWA (NVWA, 2020), there were products that contained preservatives and a *Bacillus*. A possible explanation for this is that the preservative has a mode of action to which the *Bacillus* species is not susceptible. For example, some preservatives are effective against moulds or against Gram-negative bacteria, and would not affect the added (Gram-positive) *Bacillus* species. If the preservatives are not well-chosen, however, the effectiveness and/or shelf life of the microbial cleaning product could be reduced.

Another explanation could be that *Bacillus* survives in a microbial cleaning product as spores, which are not susceptible to the preservative present in the product. A definite explanation for the survival of *Bacillus*

in microbial cleaning products containing preservatives could not be found in this project.

On the other hand, some products did not seem to contain any preservatives. If the preservatives in microbial cleaning products are not present or not functioning as intended, the product may easily become infected by (possibly pathogenic) microorganisms from the surroundings. At the same time, the necessity for preservatives could differ between products. For example, pressurised spray products like deodorants are unlikely to be susceptible to contaminations from the outside due to the pressure. Other products, such as hand gels, may contain solvents as alcohol and isopropanol preventing the growth of (unwanted) microorganisms.

Unfortunately, the information available was not sufficient to investigate the effectiveness of the preservation systems in the microbial cleaning products found. Therefore, the potential risk of contamination with and spreading of pathogenic microorganisms by products with insufficient preservation systems could not be assessed in this report. More research is needed to clarify to what extent microbial cleaners contribute to the spreading of pathogenic microorganisms. Future research may focus on the effectiveness of the preservation systems as well as on the (unintended) presence of pathogenic microorganisms in microbial cleaners.

6.2 Regulatory frameworks

Microbial cleaning products may fall within the scope of the frameworks on Detergents, on Cosmetics, on Biocidal products (BPR) and the more general Commodities Act. It is often not clear which framework applies; it is often especially unclear whether a product is a biocide or not.

Currently, whether a product is seen as a biocide mostly depends on the claim a producer puts on the product. In the market analysis, some products were found with biocidal claims and when the products were checked later, the claim was changed. This may be done to make sure the product is not classified as biocidal product and to prevent the requirement of authorisation of the biocidal product.

The approval of *Bacillus amyloliquefaciens* as an active substance for biocides shows that microbial cleaning products can be placed under the BPR. Recent legal ruling ('Darie-arrest': CJEU, 2019) shows that microbial cleaning products can be placed under the BPR, despite the lack of a biocidal claim.

The current discussion on hydroalcoholic hand gels in the European Union could lead to the decision that secondary biocidal claims are not allowed anymore on hand gels under the Regulation on Cosmetic Products. This might lead to the situation that more or even all products with a secondary biocidal claim will fall within the scope of the BPR.

6.3 Potential risks

Microorganisms present in microbial cleaning products may potentially pose a risk to humans, animals and the environment. This depends on the hazard (the microorganism present and the effects it may cause) and on the exposure (exposure routes and amounts).

Hazards related to microorganisms include infection, intoxication, irritation and hypersensitivity reactions and contribution to antimicrobial resistance.

The *Bacillus* species found may all be regarded as potentially irritating and sensitising. One product contained *Bacillus cereus*, a pathogenic species that may produce intoxication after oral exposure. In addition, several *Bacillus* species are reported to contain antimicrobial resistance genes and may contribute to the spread of antibiotic resistance.

In general terms, exposure to microorganisms in microbial cleaning products may occur via skin contact, ingestion or inhalation and exposure may lead to infection and related illness.

The information needed to quantitatively assess the risk is often not available. It is difficult to quantitatively calculate exposure to microorganisms via microbial cleaning products, as microorganisms may increase or decrease in numbers during production, storage and use. This may even go on after cleaning if the microorganism is present on the cleaned surface.

6.4 Ways to ensure safety of microbial cleaning products

One way to ensure the safety of microbial cleaning products could be to classify them as biocidal products so they will fall within the scope of the BPR. In this way, both the assessment and the control of safety issues are covered.

A disadvantage of bringing all microbial cleaning products within the scope of the BPR, is that the authorisation is a long and costly procedure.

Successfully bringing microbial cleaning products within the scope of the BPR should be a coordinated European action.

Another way to ensure the safety of microbial cleaning products could be to create a new regulatory framework for microbial cleaning products.

The framework could be based on the existing risk assessment methods for microorganisms as currently in use in the regulatory frameworks for food and feed, for biocides and for plant protection products.

The QPS approach in the food and feed framework only takes into account oral exposure. For many microbial cleaning products found, producers refer to QPS to state that the microorganisms used in their products are safe. As dermal exposure and inhalation are relevant exposure routes for microbial cleaning products, referring to the QPS status of a bacterial species is not sufficient.

The potential risks related to microbial cleaning products – including irritation and sensitisation, spreading of AMR and possible contamination with pathogenic microorganisms – that were identified in this report emphasise the need for a regulatory framework that ensures the safety of these products. It is therefore recommended to further explore the possibilities and challenges of both options mentioned above.

6.5 Overall conclusion

In conclusion, the product group of microbial cleaning products is very diverse, and information on the products is often incomplete. It is often

unclear which regulatory framework applies. The commonly applied frameworks for detergents and cosmetics do not include any data requirements on the safety of products with added microorganisms. Cosmetic products and detergents have to comply to the general requirement that products on the market should be safe under normal conditions of use. The most relevant risks for the *Bacillus* species found in microbial cleaning products are irritation after exposure to eyes, skin or via inhalation and the development of contact allergy after exposure via skin or via inhalation.

7 Abbreviations

AMR	Antimicrobial Resistance
BIT	Benzisothiazolinone
BOS	Biocidenoverleg Statusbepaling
BPR	Biocidal Products Regulation
CBG-MEB	College ter Beoordeling van Geneesmiddelen; Medicines Evaluation Board
Ctgb	College voor de toelating van gewasbeschermingsmiddelen en biociden; Dutch Board for the Authorisation of Plant Protection Products and Biocides
EC	European Commission
eCA	evaluating Competent Authority
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EU	European Union
GPSD	General Products Safety Directive
GMO	Genetically Modified Organisms
IGJ	Inspectie Gezondheidszorg en Jeugd; Health and Youth Care Inspectorate
ILT	Inspectie voor Leefomgeving en Transport; Human Environment and Transport Inspectorate
INCI	International Nomenclature of Cosmetic Ingredients
I&W	Ministerie van Infrastructuur en Waterstaat; Ministry of Infrastructure and Water Management
MIT	Methylisothiazolinone
NVWA	Nederlandse Voedsel- en Warenautoriteit; Netherlands Food and Consumer Product Safety Authority
NVWA-BuRO	Bureau Risicobeoordeling en Onderzoek van de Nederlandse Voedsel- en Warenautoriteit; Office for Risk Assessment & Research of the Netherlands Food and Consumer Product Safety Authority
PPP	Plant Protection Products
PT	Product Type
QPS	Qualified Presumption of Safety
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals

8 Terminology

Active substance	An active substance in a biocidal product is a substance or microorganism with an action on or against harmful organisms.
Bacillus	A genus of Gram-positive bacteria consisting of many different species. Bacillus species are ubiquitous in nature and are present in for example soil. Many microbial cleaning products found in this project contain Bacillus species.
Bacillus ferment	The INCI (international nomenclature of cosmetic ingredients) name for the product obtained by the fermentation of Bacillus. Bacillus ferment is listed in the ingredients of several microbial personal care products. The term 'Bacillus ferment' does not indicate whether the Bacillus is present in the fermentation product and also does not indicate what species.
Biocidal product	Any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action, or Any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.
Cleaning	The act of making clean, meaning the removal of dirt or stains and/or the removal of unpleasant odours.
Cosmetic product	Any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes

of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.

Detergent	Any substance or mixture containing soaps and/or other surfactants intended for washing and cleaning processes.
Microbial cleaning product	Products meant for cleaning purposes that contain microorganisms in order to perform or facilitate the cleaning process. It includes not only household cleaners but also cleaning products for body and hair (personal care products, animal care products) or cleaning products for instruments and tools. Microbial cleaning products do not include leaning products containing enzymes but not microorganisms.
Surfactant	Any substance or mixture containing soaps and/or other surfactants intended for washing and cleaning processes". Subsequently, surfactants are defined as "any organic substance and/or mixture used in detergents, which has surface-active properties and which consists of one or more hydrophilic and one or more hydrophobic groups of such a nature and size that it is capable of reducing the surface tension of water, and of forming spreading or adsorption monolayers at the water-air interface, and of forming emulsions and/or microemulsions and/or micelles, and of adsorption at water-solid interfaces.
Treated article	Any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products. A microbial cleaning product containing a preservative could be a treated article. The biocidal active substance used in treated articles must be approved.

9 References

Chang M and Chang HC. Development of a screening method for biogenic amine producing *Bacillus* spp. *International Journal of Food Microbiology*, 2011; 153 (3): 269-274.

CJEU, 2012. Court of Justice of the European Union, Judgment of the Court (Third Chamber) of 1 March 2012. Söll GmbH v Tetra GmbH. In Case C-420/10.
<http://curia.europa.eu/juris/document/document.jsf?text=&docid=119906&pageIndex=0&doclang=en&mode=lst&dir=&occ=first&part=1&cid=1460038>

CJEU, 2019. Court of Justice of the European Union, Judgment of the Court (Ninth Chamber) of 19 December 2019. Darie BV v Staatssecretaris van Infrastructuur en Milieu. Request for a preliminary ruling from the College van Beroep voor het Bedrijfsleven. ECLI identifier: ECLI:EU:C:2019:1140
<http://curia.europa.eu/juris/celex.jsf?celex=62018CJ0592&lang1=nl&type=TEXT&ancre=>

Ctgb, 2018. Evaluation Manual for the Authorisation of biopesticides according to Regulation (EC) No 1107/2009. Microorganisms, Botanicals and Semiochemicals; version 1.1; July 2018.
<https://english.ctgb.nl/plant-protection/assessment-framework/biopesticides-evaluation-manual>

EC, 2000. Directive 2000/54/EC of the European Parliament and of the Council on the protection of workers from risks related to exposure to biological agents at work (Directive)
<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02000L0054-20200624>

EC, 2004. Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on Detergents
<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02004R0648-20150601&from=EN>

EC, 2006. Regulation (EC) no 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency
<https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:02006R1907-20200428>

EC, 2009a. Regulation (EC) no 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products
<https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32009R1223&from=EN>

EC, 2009b. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32009R1107>

EC, 2011. Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products.

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02011R0546-20180524>

EC, 2012. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02012R0528-20191120>

EC, 2013a. 2013/674/EU Commission Implementing Decision of 25 November 2013 on Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products.

<https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32013D0674>

EC, 2013b. Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1602092104793&uri=CELEX:02013R0283-20141117>

EC, 2013c. Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02013R0284-20150917>

EC, 2013d. Note for guidance. Subject: Borderline between the legislation for cosmetics and biocides. CA-Jul13-Doc.5.1.h.

<https://english.ctgb.nl/documents/assessment-framework-biocides/2017/09/21/borderline-between-the-legislation-for-cosmetics-and-biocides---scope-bpr>

EC, 2016. Guidance document for Applicants on preparing Dossiers for the Approval or Renewal of Approval of a Micro-organisms including Viruses according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013. SANCO/12545/2014- rev. 2 March 2016.
https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_applicants-microbial_en.pdf

EC, 2020. Guidance on the applicable legislation for leave-on hand cleaners and hand disinfectants (gel, solution, etc.), March 2020
https://ec.europa.eu/growth/sectors/cosmetics/products/borderline-products_en

ECHA, 2017. Guidance on the Biocidal Products Regulation, Volume V, Guidance on Active Micro-organisms and Biocidal Products. Version 2.1, 2017. DOI: 10.2823/31176.

EFSA, 2014. European Food Safety Authority. Explanatory Note for the Guidance of the Scientific Panel of Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) on the Submission of a Dossier on Food Enzymes. EFSA supporting publication 2014:EN-689.

EFSA, 2017. European Food Safety Authority. Scientific Opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA. EFSA Journal, 2017; 15 (3): 4664.

EFSA, 2018. European Food Safety Authority. Guidance on the characterisation of microorganisms used as feed additives or as production organisms. EFSA Journal, 2018; 16 (3): 5206.

EFSA, 2020a. European Food Safety Authority. Update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 12: suitability of taxonomic units notified to EFSA until March 2020. EFSA Journal, 2020; 18 (7): 6174.

EFSA, 2020b. European Food Safety Authority. The 2019 updated list of QPS status recommended biological agents in support of EFSA risk assessments. EFSA Journal, 2020; 18 (2): 5966.

Ehling-Schulz M, Lereclus D, Koehler TM. The Bacillus cereus Group: Bacillus Species with Pathogenic Potential. Microbiology spectrum, 2019; 7 (3): :GPP3-0032.

ILT, 2017. Leidraad voor de bepaling van de grens tussen reinigingsmiddelen en desinfecteermiddelen (biociden).
<https://www.ilent.nl/documenten/publicaties/2017/08/01/leidraad-voor-de-bepaling-van-de-grens-tussen-reinigingsmiddelen-en-desinfecteermiddelen-biociden>

Lee NK, Kim WS and Paik HD. Bacillus strains as human probiotics: characterization, safety, microbiome, and probiotic carrier. Food Science and Biotechnology, 2019; 28: 1297–1305.

NVWA, 2009. Systematiek voor het indelen van grensvlakproducten als geneesmiddel, cosmeticum, medisch hulpmiddel, biocide of waar.
<https://www.nvwa.nl/documenten/consument/consumentenartikelen/n-n-food/biociden/systematiek-voor-het-indelen-van-grensvlakproducten>

NVWA, 2020. Biologische reinigers: Onderzoek naar de toepassingen en het veiligheidsrisico.
<https://www.nvwa.nl/documenten/consument/consumentenartikelen/n-n-food/in-huis/inspectieresultaten-biologische-reinig-ers-2019>

Rooney AP, Price NPJ, Ehrhardt C, Swezey JL and Bannan JD. Phylogeny and molecular taxonomy of the *Bacillus subtilis* species complex and description of *Bacillus subtilis* subsp. *inaquosorum* subsp. nov.. International Journal of Systematic and Evolutionary Microbiology, 2009; 59: 2429–2436.

SCCS, 2016. The SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation. 9th Revision. SCCS/1564/15
https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_190.pdf

SCCS, 2018. The SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation. 10th Revision. SCCS/1602/18
https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_224.pdf

Stenfors Arnesen LP, Fagerlund A, Granum PE. From soil to gut: *Bacillus cereus* and its food poisoning toxins. FEMS Microbiology Reviews, 2008; 32 (4): 579–606.

Taitt CR, Leski TA, Chen A, Berk KL, Dorsey RW, Gregory MJ, Sozhamannan S, Frey KG, Dutt DL, and Vora GJ. A Survey of Antimicrobial Resistance Determinants in Category A Select Agents, Exempt Strains, and Near-Neighbor Species. International Journal of Molecular Sciences, 2020; 21: 1669.

Working group on Cosmetic Products, 2020. Manual of the Working group on Cosmetic Products (sub-group on Borderline Products) on the scope of application of the Cosmetics Regulation (EC) no 1223/2009 (art. 2(1)(a)), version 5.2, September 2020.
<https://ec.europa.eu/docsroom/documents/42850>

Annexes

Annex 1: Search strategy

An online search was performed for microbial cleaning products sold on the websites of Dutch web shops. Considering the fact that there is a vast and changing amount of such products sold on the internet, the goal of this search was not to identify all products. Instead, the goal was to obtain a thorough overview of the types of products that are sold on Dutch web shops at the time of the search.

Terms used to search for products include 'biologisch' (biological), 'probiotisch' (probiotic), 'probiotica' (probiotics), 'reiniger' (cleaner), 'schoonmaakmiddel' (cleaning product/agent), 'microbiologisch' (microbiological). Different combinations of these terms were used and websites advertising microbial cleaning products often referred to other websites on which microbial cleaning products were sold.

A criterion for the selection of the search results was that only products claimed to contain microbes were included. Products containing only enzymes for their cleaning effect were not considered.

The term 'microbial cleaning products' is considered in a broad manner; cleaning products for skin and hair (personal care products, animal care products), cleaning products for animal housing and cleaning products for instruments and tools were also considered.

No products have been purchased for this project, so apart from products analysed by the NVA (NVA, 2020) the product information was based on the information on the advertising websites. For the majority of products found through the online search, information about the product was limited to the advertisement text. Websites of the producer were consulted and information was retrieved from summary data sheets and packaging/labels if available.

In addition to the online search, the products discussed during meetings of the 'Biocidenoverleg Statusbepaling' (BOS) between January 2015 and January 2020 were screened for microbial cleaning products. The BOS is a reoccurring meeting (four times a year) of the Human Environment and Transport Inspectorate (ILT), the Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb), the NVA, the Health and Youth Care Inspectorate (IGJ), the Medicines Evaluation Board (MEB), the RIVM and the Ministry of Infrastructure and Water Management (I&W). During these meetings, products that could fall within the scope of the BPR due to their claim and/or chemical composition are discussed in order to draw conclusions whether they should be regarded as biocides or not. Any microbial cleaning products found in the BOS documentation were added to the results of this report. Products that were concluded in the BOS to be biocides were not selected.

Also, product information was retrieved from chemical analyses of products performed by the NVWA (NVWA, 2020). The aspects addressed included type of bacteria used in products, concentrations of bacteria, claims on the label, the application and form in which the products were used.

For the products found in this project, information was gathered on the application and use, on the microorganism(s) present in the product, the chemical composition (including the presence of preservatives) and claims used in their advertisement.

Annex 2: Products found

Product type	Form	Claims	Microorganism	Composition
Household cleaners				
all purpose cleaner for sport materials	spray	works on microscopic level; long-lasting effect	Bacillus amyloliquefaciens spp plantarum and Bacillus licheniformis	Non-ionic surfactants, phosphonates, Perfumes, Preservatives
spray for prevention of sweat odor on sport products	spray	safe; effective; prevents odours	Bacillus majavensis and Bacillus subtilis	Bacillus ferment, aqua, parfum.
odor removing preparation with cleaning properties	concentrated liquid, can be diluted or used as spray	removes odours; breaks down dirt	Bacillus amyloliquefaciens spp plantarum and Bacillus licheniformis	isopropanol, rest is unknown
all purpose cleaner, degreaser	concentrated liquid		bacillus altitudis and Bacillus licheniformis	unknown
all purpose cleaner	concentrated liquid	removes odours	bacillus subtilis	Sodium Lauryl Ether Sulphate, rest is unknown
sanitary cleaner	concentrated liquid	removes odours	Bacillus amyloliquefaciens spp plantarum, bacillus cereus and Bacillus licheniformis	unknown
all purpose cleaner	concentrated liquid	removes odours/dirt; long-lasting effect	bacillus subtilis	Non-ionic surfactants, phosphonates, Polycarboxylates, enzymes, Perfumes, Preservatives, Bacillus ferment

Product type	Form	Claims	Microorganism	Composition
Household cleaners				
spray for textile and for pet materials	spray	removes odours; lowers risk of disease; protective for environment	bacillus amyloliquefaciens and bacillus subtilis	unknown
dish soap	concentrated liquid	promotes environment; lowers risk of disease; prevents odours	bacillus licheniformis and bacillus subtilis	Non-ionic surfactants, amphotere surfactants, Polycarboxylates, Preservatives, Bacillus ferment
all purpose cleaner	concentrated liquid	breaks down dirt; protects surfaces from dirt	bacillus subtilis	unknown
cleaner for bedpans, urinals, toilet seats and toilets	spray	removes dirt; prevents odours; introduces healthy microbes; long-lasting effect; thorough effect; safe	bacillus megaterium and bacillus subtilis	unknown
carpet cleaner	liquid ready for use	thorough effect; removes dirt and odours	bacillus subtilis	unknown
cleaner for garbage bins	concentrated liquid	environment friendly; removes dirt and odours; safe; prevents odours	unknown	unknown
all purpose cleaner	concentrated liquid	effective; safe; removes odours; long-lasting effect	unknown	unknown
all purpose cleaner	concentrated liquid	long-lasting effect; natural; lower risk of disease; environment friendly; promotes environment; biodegradable	unknown	unknown
all purpose cleaner	concentrated liquid	thorough effect; long-lasting effect	unknown	Non-ionic surfactants, perfumes, preservatives (methylisothiazolinone)

Product type	Form	Claims	Microorganism	Composition
Household cleaners				
odor remover	concentrated liquid	removes odours	unknown	Unknown
odor remover	spray	removes odours; safe; environment friendly; long-lasting effect	unknown	water, microorganisms, smell absorber, orange & basil aroma
air freshener	spray	safe; removes odours	unknown	water, preservative(s), (bio)solution(s), perfumes, non-ionic surfactants, performance-enhancing substances, probiotic cultures, viscosity modifier, pigments
cleaner for garbage bins	liquid	removes odours	Bacillus Subtilis, Bacillus Lichniformis, Bacillus Megaterium and Bacillus Amyloliquefaciens	unknown
sanitary cleaner	concentrated liquid	removes odours; thorough effect	unknown	unknown
sanitary cleaner	concentrated liquid	removes odours	unknown	unknown
sanitary cleaner	liquid	removes odours; introducing healthy microbes; thorough effect; long-lasting effect; environment friendly; lowers risk of disease; biodegradable; safe	unknown	unknown
sanitary cleaner	spray	long-lasting effect; removes odours;	unknown	unknown

Product type	Form	Claims	Microorganism	Composition
Household cleaners				
spray for mildly dirty surfaces	spray		unknown	unknown
floor cleaner	liquid	introducing healthy microbes; safe; removes odours	unknown	unknown
floor cleaner	liquid	safe; breaks down dirt	unknown	unknown
floor cleaner; surface cleaner	concentrated liquid	thorough effect; removes odours; introduces healthy microbes	unknown	unknown
toilet cleaner	liquid	removes fat and dirt	unknown	Aqua, Micro-organism, Alkyl polyethylene glycol ethers, perfume
surface cleaner	liquid	safe; biodegradable	unknown	unknown
odor remover for sport articles	spray	long-lasting effect; removes odours; biodegradable	unknown	unknown
laundry detergent	concentrated liquid	promotes environment; removes odours	bacillus ferment	Non-ionic surfactants, phosphonates, Polycarboxylates, enzymes, Perfumes, Preservatives (Methylisothiazolinone), Bacillus ferment
spray	spray	promotes environment	bacillus ferment	unknown
all purpose cleaner	concentrated liquid	thorough effect; works on microscopic level; removes and prevents odours; introduces healthy microbes; lowers risk of disease	unknown	unknown

Product type	Form	Claims	Microorganism	Composition
Household cleaners				
laundry detergent	concentrated liquid	long-lasting effect; thorough effect; removes odours; natural	unknown	unknown
dish soap	concentrated liquid	environment friendly; safe; removes odours	unknown	unknown
interior cleaner	concentrated liquid	long-lasting effect; introduces healthy microbes; removes odours	unknown	unknown
sanitary cleaner	unclear	breaks down dirt; removes odours	unknown	surfactants
spray for preventing sweat odor	spray	prevents odours	unknown	unknown

Product type	Form	Claims	Microorganism	Composition
Personal care products				
cleaner for tooth brushes and dentures	concentrated liquid in ampoule	promotes environment; lowers risk of disease; long-lasting effect; natural	bacillus subtilis	unknown
skin spray	spray	lowers risk of disease	bacillus amyloliquefaciens, bacillus subtilis	Aqua, Bacillus ferment, Perfume, preservatives
bath foam	concentrated liquid	protective	bacillus licheniformis and bacillus subtilis	Aqua, surfactants, Bacillus ferment, preservatives, colorants, perfume
spray for facial care	spray	removes odours; lowers risk of disease	bacillus ferment	Aqua, bacillus ferment, methylisothiazolinone.

Product type	Form	Claims	Microorganism	Composition
Personal care products				
skin cream	cream	promotes environment; protective	bacillus ferment	Aqua, Glycerin, Caprylic/Capric triglyceride, Sodium polyacrylate, Ethylhexyl stearate, Trideceth-6, Bacillus ferment, Phenoxyethanol, Ethylhexyl glycerin, Parfum, Hexyl cinnamal, Benzyl salicylate, Linalool, Butylphenyl methylpropional, Benzyl alcohol, Citronellol, Coumarin, Eugenol, Alpha-isomethyl ionone, Geraniol, Hydroxyisohexyl 3-Cyclohexene carboxaldehyde, Amyl cinnamal.
shower gel	concentrated liquid	long-lasting effect	unknown	unknown
deodorant	spray	promotes environment; natural; removes odours; long-lasting effect	bacillus ferment	Aqua, Bacillus ferment, Parfum, Methylisothiazolinone
shower gel	concentrated liquid	thorough effect	bacillus ferment	Aqua, Bacillus Ferment, Sodium Laureth Sulfate, Cocamidopropyl Betaine, PEG-4 Rapeseedamide, Phenoxyethanol, Sodium Chloride, Ethylhexyl Glycerin, CI 42051, Parfum

Product type	Form	Claims	Microorganism	Composition
Personal care products				
skin cream	cream	protective; lowers risk of disease	bacillus ferment	Aqua, Bacillus Ferment, Glycerin, Caprylic/Capric Triglyceride, Sodium Polyacrylate, Ethylhexyl Stearate, Trideceth-6, Phenoxyethanol, Inulin, Ethylhexyl Glycerin, Perfume
facial spray	spray	introducing healthy microbes	bacillus ferment	Aqua, Bacillus Ferment, PEG-40 Hydrogenated Castor Oil, Phenoxyethanol, Ethylhexyl Glycerin, Perfume
shower gel/shampoo	concentrated liquid	promotes environment; lowers risk of disease; thorough effect; removes odours	bacillus ferment	Aqua, Sodium Laureth Sulfate, Cocamidopropyl Betaine, PEG-4 Rapeseedamide, Bacillus Ferment, Phenoxyethanol, Sodium Chloride, Ethylhexyl Glycerin, CI 42051, Perfume, Hexyl Cinnamal, Benzyl Salicylate, Linalool, Butylphenyl Methylpropional, Benzyl Alcohol, Citronellol, Coumarin, Eugenol, Alpha-Isomethyl Ionone, Geraniol
deodorant	spray	natural; removes odours; long-lasting effect; introducing healthy microbes	bacillus ferment	Isobutane, Propane, Alcohol denat., Butane, Bacillus Ferment, Isopropyl Alcohol, Perfume

Product type	Form	Claims	Microorganism	Composition
Personal care products				
foot spray	spray	prevents odours; safe	bacillus ferment	Aqua, Nitrogen, Bacillus Ferment, Dimethicone, Phenoxyethanol, Ethylhexyl Glycerin, Perfume
skin spray	spray	introducing healthy microbes; natural; disinfects	bacillus ferment	Aqua, Nitrogen, Bacillus Ferment, Dimethicone, Phenoxyethanol, Ethylhexyl Glycerin, Perfume.
body lotion	liquid ready for use	protective; introduces healthy microbes; lowers risk of disease	bacillus ferment	Aqua, Glycerin, Caprylic/Capric Triglyceride, Sodium Polyacrylate, Ethylhexyl Stearate, Trideceth-6, Bacillus Ferment, Phenoxyethanol, Inulin, Ethylhexyl Glycerin, Perfume, Hexyl Cinnamal, Benzyl Salicylate, Linalool, Butylphenyl Methylpropional, Benzyl Alcohol, Citronellol, Coumarin, Eugenol, Alpha-Isomethyl Ionone, Geraniol, Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde, Amyl Cinnamal.

Product type	Form	Claims	Microorganism	Composition
Personal care products				
hand gel	liquid ready for use	protective; lowers risk of disease; long-lasting effect	bacillus ferment	Alcohol denat., Aqua, Bacillus Ferment, Triethanolamine, MEK, Isopropyl Alcohol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, CI 42051, Denatonium Benzoate, Perfume

Animal housing products				
cleaner for urine stains and odors of cats and other pets	spray	removes odours and stains	bacillus amyloliquefaciens spp plantarum, bacillus subtilis	water, non-ionic surfactants, enzymes, detergent, perfumes.
cleaner for organic stains	spray	removes odours and stains	Bacillus licheniformis	Aqua, alcohol, Bacterial spores, surfactants, perfume, preservatives
foam cleaner for animal stays	concentrated liquid	thorough effect; removes odours	bacillus subtilis	unknown
cleaner for animal odors	concentrated liquid	removes odours; natural	bacillus licheniformis	non-ionic surfactants, perfumes,
cleaner for reducing ammonia, particulate matter and odors in stables	concentrated liquid	promotes environment; removes odours, fine particles and ammonia	bacillus amyloliquefaciens, bacillus licheniformis	unknown

Animal housing products				
cleaner for urine and sweat odors	liquid	removes odours	unknown	unknown
cleaner for odors in animal stables and surfaces	liquid	removes and prevents odours	unknown	unknown
cleaner for animal stables	concentrated liquid	thorough effect; introducing healthy microbes	unknown	water, non-ionic surfactants, microorganisms, smell absorber, emulsifier (ricinus oil), citric aroma, pH stabilizer, pigment
cleaner for stables/dust, ammonia and odors	spray	removes odours and ammonia	Bacillus spp.	Surfactants, preservatives, perfume
stable cleaner	concentrated liquid	promotes the environment; lowers risk for zoonoses	unknown	unknown
stable cleaner	concentrated liquid	thorough effect; breaks down dirt; long-lasting effect	unknown	unknown
stable cleaner	concentrated liquid	breaks down dirt; removes odours and fine particles	unknown	unknown
disinfection of stables/soaking agent	soaking foam	long-lasting effect	unknown	unknown
horse stable cleaner	concentrated liquid	works on microscopic level; removes odours; introduces healthy and safe microbes	unknown	unknown

Animal care products				
dental cleaner pets	spray	works on microscopic level; safe	unknown	water, microorganisms, surfactants, pH stabilizer, emulsifier (ricinus oil), chicken aroma and taste
eye cleaner pets	spray	breaks down dirt; lowers risk of disease; biodegradable	unknown	water, microorganisms, pH stabilizer
pet shampoo	liquid	introducing healthy microbes	unknown	unknown
pet shampoo	concentrated liquid	safe; removes odours; lowers risk of disease	bacillus ferment	Aqua, Acrylates/Stearaeth-20 Methacrylate Copolymer, Cocamide DEA, PEG-6-Caprylic/Capric glycerides, Sodium laureth sulfate, Bacillus ferment, Phenoxyethanol, Ethylhexyl glycerin, CI 19140, CI 42051, Perfume
pet shampoo	spray	removes odours	bacillus ferment	Preservatives: Methylisothiazolinone, Perfume, Bacillus Ferment.
animal spray	spray	removes odours; introduces healthy microbes; lowers risk of disease	bacillus ferment	Preservatives: Methylisothiazolinone, Perfume, Bacillus Ferment.
animal spray	spray	removes odours; introduces healthy microbes; lowers risk of disease	bacillus ferment	Preservatives: Methylisothiazolinone, Perfume, Bacillus Ferment.
horse shampoo	concentrated liquid	introduces healthy and safe microbes	unknown	unknown

Garden products				
algae removal		breaks down dirt		
artificial grass	liquid		unknown	unknown
artificial grass cleaner	liquid	destroys traces of moss and algae; destroys algae; removes odours	unknown	unknown
water cleaner ponds	liquid	prevents algae growth	unknown	unknown
Other products				
cleaner for sewage, septic tanks and grease traps	liquid ready for use	breaks down natural and mineral oils and fats	bacillus pumilus, bacillus subtilis	unknown
cleaner for heat exchanger and airco	liquid ready for use	thorough effect; removes dust, mould and dirt; safe; removes odours; long-lasting effect; environment friendly	unknown	unknown
cleaner for heat exchanger and airco	spray	thorough effect; removes dust, mould and dirt; safe; removes odours; long-lasting effect; environment friendly	unknown	unknown
drain unblocker	liquid ready for use	thorough effect; safe	bacillus licheniformis	unknown
drain unblocker	liquid ready for use	safe; environment friendly; long-lasting effect; removes odours	unknown	unknown
water cleaner	liquid	breaks down dirt; prevents odours	unknown	alkylethersulphate, sodium salt, sodium nitrate
cleaner for heat exchanger	spray	prevents odours; lowers risk of disease	unknown	unknown
waterbed conditioner	liquid	combats unwanted organisms	unknown	unknown
antifungal treatment walls	spray	prevents mould	Bacillus ferment	unknown
airco cleaner	spray	prevents odours	bacillus ferment	alifactic hydrocarbons (ethanol), perfume

Other products				
airco cleaner	spray	breaks down dirt; long-lasting effect; natural; safe; environment friendly; promotes environment; lowers risk of disease	unknown	unknown
Cleaning spray for face masks	spray	natural; lowers risk of disease;	bacillus ferment	Aqua, Bacillus ferment, perfume, methylisothiazolinone.

