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Environmental, Health and Legal Aspects of Cleaners Containing Living Microbes as Active Ingredients

Results and conclusions of a study commissioned by the Austrian Federal Ministry of Agriculture, Forestry, Environments and Water Management

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Das IFZ ist der Grazer Standort des Instituts für Technik- und Wissenschaftsforschung der Alpen-Adria-Universität Klagenfurt

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1 This Paper

This paper summarises the results and conclusions of a study commissioned by the Austrian Federal Ministry of Agriculture, Forestry, Environment and Water Management, Vienna and conducted by the IFZ – Inter-University Research Centre for Technology, Work and Culture.[1]

2 Motivation and Objective

Over the recent years Austrian consumer and environmental organisations have become increasingly aware of a novel type of cleaner containing living microorganisms as active ingredients (subsequently termed microbial cleaner). Given the lack of publicly available information these organisations highlighted difficulties in considering these products when providing recommendations to the public and private sector for environmental sound procurement. Information was particularly scarce on environmental properties, health risks and efficacy. It was also not clear which legal regulations are governing the safety and marketing of these products. In response to these uncertainties the Austrian Federal Ministry of Agriculture, Forestry, Environment and Water Management contracted out to the IFZ – Inter-University Research Centre for Technology, Work and Culture a study to provide advice on these questions.

3 Objective and Study Approach

The objectives of this study were (i) to provide an overview on the technology, products, and applications, (ii) to discuss the application of existing legislation, (iii) to identify and discuss possible environmental and health risks as well as environmental benefits, and (iv) to provide recommendations to regulators for further research and policy action.

The study is based on a literature review (scientific literature, "grey literature", patents, company documents, regulatory and policy document, web-based information) and on interviews and consultations with representatives of manufacturers, blenders, professional cleaning service operators, governmental authorities, consumer and environmental organisations, and scientists. The overall focus is on the EU context with a particular emphasis in Austria, though information on the USA and Canada was also considered. A draft report was discussed at a stakeholder workshop. Based on this workshop, as well as further consultations with manufacturers and additional expert interviews this draft was then revised and extended to a final report in German

[1] Spök A., Klade M. (2009). Ökologische, gesundheitliche und rechtliche Aspekte von Reinigungsmitteln mit Mikroorganismen als Wirkprinzip (mikrobiologische Reiniger). Projektendbericht. A full version of the study is available in German language only and can be obtained from the website of the Austrian Federal Ministry of Agriculture, Forestry, Environment and Water Management, Vienna at http://hilfe.lebensministerium.at/article/articleview/80941/1/7033/.

language. In order to allow for a wider circulation an extended executive summary of this report was prepared in English and circulated for comments among selected stakeholders before it was completed.

A particular difficulty arose from the overall lack of information in the public domain, from the fact the manufacturers and blenders are not well represented in professional associations and, therefore, are difficult to identify, and from the reluctance of these business operators to share information which they consider as confidential business information. This was especially challenging as a wide range of applications and product designs was identified and because producers differ broadly in terms of production processes as well as quality and safety assurance.

4 What is the Rationale of Using Microbes?

The overall rationale for using microbes is similar for all types of products. Living microbes are capable of enzymatically degrading substances associated with soil and/or bad odour. Thus, products containing spores[2] – dormant microbes - have to allow for a germination step first to the vegetative state to become physiologically active. Microbial action is aimed at control odour and to support the cleaning action of detergents. Producers of microbial cleaners are frequently making environmental and efficacy claims.

Some microorganisms produce a broad range of extracellular enzymes including proteases, cellulases, amylases, and ureases which can degrade organic high molecular weight substances in soil. As opposed to cleaners with added enzymes, microbes can further metabolise (some of) these degradations products. Substances creating odour problems such as NH_3 can be metabolised, or the formation of H_2S may be avoided by transforming SO_3 into S_2. The microbes used in the cleaning products are also claimed to out-compete unwanted microorganisms in colonising surfaces by using up the nutrients provided in the soil and from polluted surfaces. Other microbes can directly inhibit the growth of unwanted microbes, for example, by lowering pH. Producers claim a long-term effect because microorganisms will stay on the treated surface (as spores) and hinder re-colonisation by unwanted microbes.

5 What Products – what Applications?

Microbial cleaner are frequently marketed directly by manufacturers which are in almost all cases of SME type (small and medium enterprises). Most operators are blenders i.e., they are purchasing the ingredients for their products from other specialised companies and blend them to yield the final products. Very few manufacturers seem to produce (all of) the microbes by themselves. This study identified some 30 manufacturers in Austria, Germany, Switzerland,

[2] Some microbes can sporulate, e.g. *Bacillus* spp. whereas other are not capable of doing so.

Belgium, The Netherlands, UK, USA, Canada, Australia and Japan. Product data sheets of 20 companies were reviewed with more in-depth investigations of the information on products from 9 selected companies. Two companies provided detailed data including confidential business information.

In commercial contexts microbial cleaners are mainly applied for odour control in cases where conventional cleaners are considered less efficient: surface cleaning in sanitary facilities, but also more broadly as surface cleaners in buildings with a lot of visitors (e.g., public buildings, schools, restaurants, canteens, hotels, production facilities, old people's home, animal shelters, vet's surgeries). Routine application by professional cleaning service companies was found, for instance, in train toilets in Austria, Germany, and The Netherlands. A professional cleaning service company confirmed, in principle, the efficacy of these products, though there were considerable differences between products, but they highlighted the very high costs with some products. Products for hospitals are presently under evaluation. Here the rationale is that microbes sometimes causing problems in hospitals are outcompeted by the microbes used in the cleaner which would – according to producer – in some areas render disinfection unnecessary.

Besides hard surface cleaning these products are also used for cleaning carpets and upholstery. Specialty products are used for cleaning drains, pipes, and grease traps in order to remove deposits, and also in industrial production in the washing of machine parts, as well as for oil spills on masonry or concrete.

Products based on Effective Microorganisms (EM®) represent a special type in terms of product design, producer, production process, and marketing. An inoculum including a combination of bacteria and fungi is manufactured by licensed companies - mainly based in Japan - and marketed worldwide by specialised EM vendors and health food shops – partly via the internet. The same and similar combinations of microbes are used for various outdoor and indoor purposes including soil enhancement, composting, as feed additive and for cleaning. EM cleaner are not only applied in all the areas described above but recommended for a much broader range of indoor cleaning applications including tiling, stove, refrigerator, pots and pans, bio-waste container, living spaces, wooden floors, closets, wardrobes, shoe cabinets, leather clothes, glass doors, washing machines, dishwashers, doormats, cars, and even as laundry detergent. Although EM products are also being used in commercial contexts and by professional cleaning services, it appears that they are more often targeting consumers.

Manufacturers contend that their products are still less efficient than conventional chemical products in terms of surface cleaning. In terms of odour control, however, these products are claimed to be superior. Unfortunately, with one possible exception - no third-party evaluation of the efficacy of microbial cleaners could be found. The absence of generally agreed upon and standardised methods for comparing the efficacy of cleaning products might be one reason for this.

6 What EU Environmental and Health Legislation is applicable?

Microbial cleaners clearly fall under the EU Directive on occupational health risks of biological agents. With respect to sectoral legislation the picture is more unclear. It seems that the EU Detergent Regulation does not apply. The EU chemical legislation REACH is rather unlikely to apply but that is not entirely clear. The EU biocide legislation might possibly apply to some, but not all, of these products. Thus, at present, no sectoral environmental legislation is clearly covering these products. If so, the EU Directive 2001/95/EC on general product safety[3] would still apply and require a certain safety assessment and risk-related information to consumers by manufacturers and importers of these products. However, there is substantial leeway on how to interpret the requirements of this Directive. Consequently, the only clear requirements established are for assessing certain risks for worker's health.

Occupational health: Microbial cleaners are covered by EU Directive 2000/54/EC which regulates the minimum requirements for the protection of workers from risks related to biological agents[4]. Employer (e.g. manufacturers and blenders of microbial products, professional cleaning service companies, other companies employing cleaning personnel) are required to conduct a risk assessment, including the classification of the microorganisms used into one of four risk groups based on the pathogenic potential[5]. Potential allergenic or toxigenic effects (especially the former, are not reflected by the risk group scheme) and exposures also have to be considered[6]. Only microbes which belong to risk group 1 are not considered to pose any hazards to human health. The use of microbes classified in risk group 2 or higher requires notification to the national competent authorities and preventive measures by the employer. The type of risk mitigation measures largely depends on the particular risk group and exposure scenario. Manufacturers claim that microbes classified into risk group 2 or higher are neither used nor considered for application in cleaners and this was essentially confirmed in the product survey – with the exception of one product for special application in outdoor contexts.

Detergent legislation: Following a company request, the European Commission and the Members States agreed that microbial cleaners - even if containing surfactants - do "not seem to have a cleaning action within the meaning of ISO definition (i.e. 'the process by which soil is dislodged from the substrate and brought into a state of solution or dispersion')" and are,

[3] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (Text with EEA relevance). *OJ L 11, 15.1.2002, p. 4–17.*

[4] Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC). *OJ L 262, 17.10.2000, p. 21–45.*

[5] Scheme included in Annex III of the Directive 2000/54/EC.

[6] Art. 3 (3d), Directive 2000/54/EC.

therefore, out of the scope of the EU Regulation on detergents.[7] However, this decision was based on an inquiry for one specific product where the cleaning action is claimed to result from bacteria feeding on the excrement of dust mites. It is not entirely clear if the rationale of this decision would also apply to all microbial products, e.g. to surface cleaner in sanitary facilities.

Chemical legislation - REACH: All chemical compounds used in microbial cleaners are covered by the new EU chemical legislation REACH. Living microorganisms and spores, however, do not meet the definition of 'substance' as they can neither be understood as 'well defined substances' nor as UVCB substances (Substances of Unknown, Variable composition, Complex reaction Products or Biological Materials).[8] Manufacturers claim that this view has been confirmed by the Dutch and the Finish national competent authorities. Still, some uncertainty remains. The Manual of Decisions of the EU chemical legislation prior to REACH explicitly excluded living (micro)organisms from the scope of the legislation[9] whereas the REACH guidance document does not[10]. It also remains unclear if the enzymes produced by the microbes and secreted outside the cells can be considered as UVCBs under REACH in analogy to enzyme (mixtures) added to cleaners. In fact, the very similar enzymes sometimes added to the microbial cleaner in addition to the microbes are covered by REACH whereas those produced by the microbes are not. Despite the absence of a legal requirement some manufacturers mention microbes in the Material Safety Data Sheets (MSDS), but not all manufacturers, and not in a consistent manner.

Biocide legislation: Some microbial cleaners could potentially be considered as biocides[11] which would then be regulated under Directive 98/8/EC[12] for a number of reasons.

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[7] European Commission (2009). Question and agreed answers concerning the correct implementation of Regulation (EC) No 648/2004 on detergents. Version: March 2009. http://ec.europa.eu/enterprise/chemicals/legislation/detergents/docs/faq_detergent_regulation_march2009.pdf.

[8] ECHA (2007): Guidance for the identification and naming of substances under REACH. http://bookshop.eu.int/eubookshop/download.action?fileName=ED3007006ENC_002.pdf&eubphfUid=10024870&catalogNbr=ED-30-07-006-EN-C.

[9] European Chemicals Bureau. Institute for Health and Consumer Protection. MANUAL OF DECISIONS FOR IMPLEMENTATION OF THE SIXTH AND SEVENTH AMENDMENTS TO DIRECTIVE 67/548/EEC ON DANGEROUS SUBSTANCES (DIRECTIVES 79/831/EEC AND 92/32/EEC) (NON-CONFIDENTIAL VERSION).Updated: 03rd July 2006; http://ecb.jrc.ec.europa.eu/documents/New-Chemicals/Manual_of_decisions.pdf; Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance) .Official Journal L 353 , 31/12/2008 P. 0001 – 1355.

[10] ECHA (2007): Guidance for the identification and naming of substances under REACH. http://bookshop.eu.int/eubookshop/download.action?fileName=ED3007006ENC_002.pdf&eubphfUid=10024870&catalogNbr=ED-30-07-006-EN-C.

[11] Biocidal products are defined in EU legislation as „active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means." (Art. 1, Directive 98/8/EC).

[12] Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market. OJ L 123, 24.4.1998, p. 1–63.

- Microorganisms can, in principle, be considered as biocides, e.g. two *Bacillus* spp. including *B. subtilis* are listed as biocides in the Annex to Regulation 1451/2007.[13] *B. subtilis* is frequently used in microbial cleaners.

- Drawing on analogies of other borderline cases it appears possible that the outcompeting of unwanted microorganisms by other microorganisms via chemical or biological mechanisms could be considered a biocidal effect *if* resulting from direct action[14]. In contrast, a 'physical' displacement of unwanted microorganisms by overgrowing with beneficial microorganisms or as a consequence of nutrient competition would presumably not be considered as biocidal activity. Manufacturers are frequently highlighting the latter effects. For many microorganisms, however, including some species applied in microbial cleaners, it is described in the scientific literature that they can inhibit cell growth or even kill other microbes by producing and releasing bactericides or fungicides. Other microbes can inhibit growth by other means, e.g. lactic acid bacteria by lowering the pH. This type of mechanism could potentially be considered a biocidal activity. So, the question here is, whether these mechanisms would also apply to some of the strains used in microbial cleaners. Any clarification of this question would require a more comprehensive description of all the mechanisms of action for each microorganism used.

- In certain cases manufacturers are making claims which could be interpreted as claiming biocidal effects, in particular in the case of microbial cleaners used in hospitals, but also for sanitary facilities, for cleaning carpets and upholstery when claiming deodorization or odour control.

According to two manufacturers, the national competent authorities in Belgium have confirmed that EU biocidal legislation does not apply to their products. A similar view was given by a Dutch Authority.[15] No information was available on other types of products, from other competent authorities or from the EU level. Consequently, the applicability of the EU biocide legislation remains to be clarified, though, most likely restricted to specific applications and mechanisms of actions.

[13] Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market . OJ L 325, 11.12.2007, p.3-65.

[14] MANUAL OF DECISIONS FOR IMPLEMENTATION OF DIRECTIVE 98/8/EC CONCERNING THE PLACING ON THE MARKET OF BIOCIDAL PRODUCTS. Last modified: 10.07.2008. http://ec.europa.eu/environment/biocides/pdf/mod.pdf; EC (2003): Guidance document agreed between the Commission services and the competent authorities of the Member States for the Biocidal Products Directive 98/8/EC. Doc-Biocides-2002/04-Rev3. 31.10.2003. http://ec.europa.eu/environment/biocides/pdf/definitions.pdf.

[15] VWA (2004): BACTERIËLE REINIGERS. Reinigers op basis van micro-organismen.met eventuele toevoegingen. Statusrapport over de werking van microbiologische reinigers, de wettelijke aspecten en eventuele gezondheidsrisico's voor de consument en professionele gebruikers. Rapport nr. ND04o071-3. VOEDSEL EN WAREN AUTORITEIT (VWA).

USA and Canada

In the USA, the use of naturally occurring microbes in microbial cleaners is not regulated. One exemption is the use of microorganisms as pesticides (biocides). However, many microbial cleaners are not applicable to US pesticide regulation. .

Canada, in contrast, does regulate living organisms by extending the definition of substance in the Canadian Environment Protection Act (CEPA). Since 1999 a notification under the New Substance Notification Regulations (NSNR) is required if a microorganism is not yet included in the Domestic Substance List (DSL).[16] The DSL presently lists some 50 microorganisms specified by strain and two combinations of microbes ('consortia').[17] However, in all these cases the producers could prove that these strains have already been used in Canada before and were, therefore, exempt from the NSNR. None of these microorganisms has undergone the fully fledged assessment of health and environmental risks required for a New Substance Notification which has specific guidance[18]. Regulators also do not as yet have information on which of the listed microorganisms are being used for microbial cleaners (Health Canada, personal communication).

7 Are Microbial Cleaner Environmentally Sound?

Producers of microbial products are frequently claiming their products to be more environmentally sound than conventional chemical cleaners because they include either no, or less harmful, chemical ingredients. A preliminary comparison by the authors of this study of product ingredients for selected microbial cleaners showed that most microbial cleaner products contain much lower levels of acids and surfactants. Microbial products used in commercial and industrial contexts for cleaning drains, pipes and grease traps are less alkaline, and indicate a potential for reducing the amount of organic solvents used. This is also true for solvent-free microbial degreasing of parts in industrial manufacturing. According to manufacturers, the preventive character of microbial action is also potentially beneficial for the environment as microbes are being active as long as there is sufficient nutrients and water on the surface. When lacking nutrients or water, certain microbes can survive as spores which can germinate and become physiologically active again if nutrients and water becomes available again. If used on a

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[16] Environment Canada (no publication year specified): Fact Sheet. Products Containing Living Micro-Organisms. http://www.ec.gc.ca/substances/nsb/pdf/360_micro_org_e.pdf.; Environment Canada (2000): New Substance Notifications Regulations Biotechnology Products. Alert. http://www.ec.gc.ca/substances/nsb/pdf/a0008_e.pdf.

[17] Environment Canada: List of organisms on the Domestic Substances List. Updated 20-08-2008. http://www.ec.gc.ca/substances/nsb/pdf/biolist.pdf.

[18] Government of Canada, Environment Canada, Health Canada (2001): Guidelines for the Notification and Testing of New Substances: Organisms. Pursuant to The New Substances Notification Regulations of the Canadian Environmental Protection Act, 1999. http://www.ec.gc.ca/substances/nsb/pdf/Bioge1201.pdf.

regular basis, for instance, in grease traps and drain pipes the formation of sediments and odour is reduced which renders the need to use environmentally harmful cleaning products unnecessary.

In general, the claims of the producers are plausible. Verification, however, would require case studies comparing individual microbial and chemical products in a systematic and quantitative way which was beyond the scope of this study.

8 Are there Health and Environmental Risks?

Microorganisms in general can be harmless to human health and the environment and many microorganisms have been used for decades and even thousands of years in the processing of food and feed. Other microorganisms are pathogenic or toxic to humans, animals or plants. Also, allergenic properties have to be considered. Microorganisms showing (a potential) for hazardous properties or having a long track record of safe use are usually described in the scientific literature and regulatory documents. For assessing the health or environmental hazards it is therefore pivotal to know the identity of the microorganisms contained in the cleaners.

Microbial cleaning products differ in the particular combination of microorganisms used and the particular chemical ingredients, including enzymes (some cleaner also contain enzymes). The combination of microorganisms and chemicals largely depend on the particular application, but there are also different product designs. In this study's product survey, producers usually considered the precise identity (species, strain) as confidential business information. Only the taxonomic genus was declared if such information was given at all. A very few producers provided more detailed information. The survey identified more than 30 different species, mostly bacteria and a few yeast and fungal species, though, in practice, the range of microorganisms might be much broader as indicated in patent literature and other documents. The most frequently used microbes are members of the genus group *Bacillus, Bifidobacterium, Lactobacillus, Rhodopseudomonas,* and *Saccharomyces*. Some producers are specialised on combinations of different *Bacillus* spp. spores instead of using vegetative cells as spores allow for a longer shelf life, up to one year.

Producers are claiming that all of their microbes belong to risk group 1 and are not posing any health concerns. Moreover, some of the microbes used in cleaners are generally recognised as safe in food and other processing contexts.[19] This is in accordance with information obtained in the product survey that all microbes identified on the species level can be classified in risk group 1. Exceptions only apply to one specialty purpose cleaner for outdoor purposes and to microbes

[19] They are considered as GRAS (Generally Recognized as Safe) and/or QPS (Qualified Presumption of Safety). Both concepts are also being used to identify microorganisms for which there are sufficient track records of safe use and handling – mainly in the food and feed production. Microbes having either a GRAS or QPS status resp. are exempted from certain risk assessment requirements.

suggested in patent literature. Some producers have also referred to additional safety reassurance from various OECD toxicity tests on rodents, although these test data are not in the public domain.

While all this suggests that there is no immediate threat for human health or the environment, this study has identified a number of issues which would need in-depth review, clarification and/or improvements. These issues also make clear why there is a need for more elaborate and harmonised risk assessment considerations by the producers – presumably under regulatory oversight:

Reliability of a key step in risk assessment – taxonomic identification – remains unclear

The classification in the risk group scheme, the assessment of potential hazardous properties, and the existence of relevant experience in safe handling (history of safe use) based on scientific literature and regulatory documents is based on a reliable identification on the species (and frequently on the strain level). It is widely acknowledged that taxonomic identification can lead to erroneous results if not based on proper methods. This is important, as sometimes even taxonomically closely related species or strains can differ considerably in their hazardous properties. For instance, some strains within the same *Bacillus* species (including some species used in cleaner) can produce enterotoxins whereas other strains are not capable of doing so.[20,21] Any erroneous identification could, thus lead to entirely different results in the hazard assessment. Furthermore microbial phylogeny and taxonomy has changed considerably over the recent 20 years - mainly due to insights from microbial genetics. These difficulties have also been recognised by the OECD which, in response, issued a guidance document for taxonomic identification of bacteria in 2003.[22]

Little information was obtained on the taxonomic identification methods used by producers of microbial cleaners. The available information suggests different practices. Some of the organisms used came from widely acknowledged national microbial strain collections (e.g. American Type Culture Collection ATCC[23]). Here the source guarantees the application of proper methods for strain identification. Other microbes, however, were isolated from natural environments by the producers of microbial cleaners. Especially with the latter type of strains and in the absence of detailed information on the identification method the reliability of the identification remains a potential concern. Sometimes, the taxonomic identification is done by the producer, in other

[20] Here, the differentiation between these strains is also important for the QPS status. Toxin producing strains are explicitly excluded from the QPS status (see EFSA 2008).

[21] EFSA (2008): SCIENTIFIC OPINION. The maintenance of the list of QPS microorganisms intentionally added to food or feed1. Scientific Opinion of the Panel on Biological Hazards (Question No EFSA-Q-2008-006). Adopted on 10 December 2008. The EFSA Journal 923, 1-48.

[22] OECD (2003) Guidance Document on the Use of Taxonomy in Risk Assessment of Micro-Organisms: Bacteria. Series on Harmonisation of Regulatory Oversight in Biotechnology No.29. ENV/KM/MONO(2003)13.

[23] http://www.lgcstandards-atcc.org/.

cases by an accredited microbiological laboratory. Also the extent of in-house capability in microbiology seems to vary among producers. Moreover, identification is not only conducted at the time when the strain is obtained once and for all - it remains to be an issue when maintaining an in-house strain collection from which inocula are being derived.

How to avoid unwanted microbes in the cleaning products

The production of sufficient quantities of microorganisms for a microbial cleaner is done by standard fermentation technology. Any fermentation process has the potential to result in unwanted microorganisms present in addition to the desired microbes. Depending on the particular process conditions these unwanted or contaminating microbes might include pathogens and/or might produce toxins. Moreover, they could also interfere with the intended microbial action. This is widely acknowledged[24] and operators of biotechnological processes have therefore established process controls and quality assurance systems aimed at both avoiding (to high levels) of and checking for contaminants.

Information from manufacturers indicated huge variations in process controls and quality assurance. In some cases this is raising doubts on hygiene, quality and consistency of the products. Such doubts are also reinforced by the findings of a study conducted by the Dutch Food and Consumer Product Safety Authority (VWA).[25] The microbiological analysis of microbiological cleaning products identified huge variations in total viable counts indicating problems with consistency and shelf life. They also found microbial contaminants including - in one case - a risk group 2 organism associated with human infections. These hygienic problems and the fact that some of the strains being used belong to microbial species known as either opportunistic pathogens or food contaminants resulted in a VWA recommendation not to use microbial cleaner in areas of food processing and preparation and also not with particular risk groups ((YOPI – young, old, pregnant, immune compromised). More recently they also advised against the use in hospitals based on the same reasons. Other applications, e.g. for sanitary purposes, are considered acceptable by the VWA.

Possible concerns in case of chronic respiratory exposure

The appropriate use of some microbial cleaner products leads to exposure scenarios which deserves particular attention. Spray application in closed rooms (e.g. toilets) can lead to aerosol formation. The repeated application on carpets and upholstery can lead to accumulation of spores and formation of dust containing spores. Used in daily cleaning, chronic respiratory exposure therefore has to be considered in health risk assessment. There is evidence in the scientific literature of sensitizing properties and of hypersensitivity pneumonitis. In its microbial pesticide program, the US EPA generally recognizes that microorganisms may be respiratory

[24] See for instance the recent discussion on the OECD level: OECD (2006): Discussion on Microbial Contaminant Limits for Microbial Pest Control Products. Draft OECD Issue Paper, 8 Sept 2006.

[25] VWA (2004) see fn 15.

sensitizers. At the present time in the course of its voluntary partnership environment label program, Design for the Environment (DfE) , the US EPA has generally excluded from consideration microbially-based products intended for use on carpets, hard surfaces and other indoor environments until further information on their safety can be obtained.[26] Allergenic properties are also described for the mould species *Aspergillus oryzae* which is also being used in some cleaners.

It is not clear whether and to what extent these hazards are caused by the microbial enzymes and/or on other components of microbial cells and spores. Sensitizing and allergenic properties of microbial enzymes, as well as some microbial cells, are well documented. A difficulty is that there is no agreed upon test for respiratory sensitization. In the EU microbial enzymes are therefore voluntarily considered by industry as respiratory sensitizers and labelled and handled accordingly (R42).[27] Further investigation of this question was, however, beyond the scope of this study.

In order to check to what extent and in what particular cases these concerns are also valid for microbiological cleaners, an in-depth scientific review needs to be conducted and quantitative data or robust estimates on the concentration of cells and spores in aerosols or dust, and the effects of those concentrations, would be required.

Environmental risks of the microbes

Little can be said on the environmental risks of the microbes used. While producers are generally keen to use safe microbes only, the risk group scheme for classifying microbes does not specifically consider plant or animal (in case there is no human pathogenicity) pathogenicity. The risk group scheme also does not consider toxicity to animals. Some companies referred to standard OECD oral toxicity tests on rodents as well as to eco-toxicity tests conducted with the *Bacillus* strains they are using and which did not – according to these producers – identify any environmental risks. This type of information does not seem to be available from all manufacturers or for all microbes.

9 What conclusions and recommendations can be drawn?

Efficacy

Compared to conventional chemical cleaners, microbial cleaning products appear to have advantages in certain applications, in particular in daily cleaning where odour control is

[26] US EPA (2009): The Design fort the Environment (DfE) Program's Supplemental Considerations for Partnership on Microorganism-based Products. Draft 6/22/09.

[27] Federal Environment Agency/Inter-University Research Center for Technology Work, and Culture (2002): Collection of Information on Enzymes. Final Report. Luxembourg: European Commission.

important and for special purposes (removal of grease, fat, oil, sediments in grease traps, drains, pipes, on masonry and concrete). Here the cleaners are acting on the causal agent instead of covering bad odour with perfumes. Odour-forming substances are degraded and/or odour forming microbes are outcompeted. For such applications microbial cleaners may be considered. Producers of microbial products should reconsider the use of perfumes in their products.

With respect to the removal of soil, microbial cleaners are - according to some manufacturers and practitioners in daily cleaning - not quite as efficient as conventional chemical products. However, given the possible preventive or long-term action of some products, studies should be initiated to compare more thoroughly the efficacy of both types of cleaners for different applications using standardised test designs.

Stakeholder and public information

There is little information about products, producers, applications to consumers, and in the public domain in general. Despite the fact that there are producers in many countries, there is no specific trade association for these producers and producers and products are difficult to track. Whether microbes are being used or not is sometimes not clearly stated, or it is expressed in roundabout ways, such as 'biological' cleaner, 'biological', 'probiotic' cleaner, etc. More transparency to consumers and stakeholders would be a prerequisite for broader adoption by consumers. A product database should be established, and the information collected in the course of this study should be expanded.

More science on the mechanism

The available information on the various mechanisms of action of the microbes is considered insufficient. This refers to a lack of transparency but also to a lack of detailed knowledge on some products. Further scientific studies should be launched to investigate the physiological and biochemical basis of these mechanisms. Such information would also be important for clarifying a possible applicability of EU biocide and detergent legislation.

Possible environmental benefits

Due to the substitution of certain chemicals, microbial action appears to be promising in terms of environmental protection. Studies should investigate and verify these potential environmental benefits in quantitative comparative analyses. Ideally a life cycle analysis should be performed which could also include a risk assessment.

Health risks

Based on the available information no clear immediate hazard could be identified. A qualification to this conclusion is that only a few producers decided to reveal the identity of their microbes to the project team. As a general pattern, risk relevant information obtained from producers was fragmentary and lacking technical detail.

As highlighted in the preceding section, some aspects deserve more attention and presumably regulatory oversight:

- The precise taxonomic identification of the microbes used as the basis of the entire risk assessment should be conducted according to OECD guidance

- The process control and quality assurance systems in place to avoid having unwanted microbes should be reviewed /included in the regulatory oversight

- The relevance of the risks associated with chronic exposure to dusts and aerosols containing vegetative cells and spores should be clarified

- The risks linked to the use of strains which belong to species known to include opportunistic pathogens and possible hazards for particular risk groups (YOPI – young, old, pregnant, immune compromised) should be clarified; this is linked to possible restrictions in, e.g. hospitals, retirement homes, child care.

- The risks associated with particular species, some strains of which are known from cases of food contamination and poisoning; should be clarified. This is linked to possible restrictions of the application in areas where food is being handled and processed.

Taking into consideration the different practices of producers in terms of risk assessment and quality assurance, a risk assessment protocol should be developed which also includes the requirements for taxonomic identification. In the course of establishing this protocol, the issues above could be clarified – even if uncertainties prevail – and the consequences for risk assessment and risk mitigation measures could be agreed upon. An internationally harmonised approach would thereby be in the interest of producers and users. Such an initiative should therefore be launched at the EU or international level, for instance at OECD.[28] A good starting point would be the already existing guidance documents established for risk assessment in the context of the Canadian New Substance Notification and for the product review in the course of the US EPA DfE programme.[29]

As long as these issues have not been properly addressed/clarified a clear-cut recommendation in favour of using microbial cleaners as spray in closed environments or for cleaning carpets and upholstery could not be provided.

Given the results of the VWA study and as long as there is no regulatory oversight the occurrence of possible harmful contaminants should be checked by a third-party. This could be done by conducting a microbial analysis of a microbial cleaner, e.g. at the beginning and the end of their shelf life. Very similar to the analysis of the VWA – which was conducted some ten years

[28] The interest to clarify the open question and set up a standard risk assessment protocol was also expressed by the Dutch, the Canadian and US competent authorities.

[29] See fn 18, 26.

ago – such a study could verify the identity and quantity of the microbes intended to be present and identify possible (harmful) contaminants.

Legislation

It is recognised that microbial cleaners represent a novel type of product which does not smoothly fit into EU chemical, detergent or biocide legislation. The applicability of either of these legislations might well depend on the particular product use and claims, thus, the adaptability of all three legislations should be further clarified. Alternatively, a specific regulation should be established tailored for these products to provide for regulatory oversight of environmental and health risks. In the absence of such a regulation the observed differences in terms of quality assurance, hygiene and risk assessment might continue which potentially leads to products which differ markedly in terms of efficacy, hygiene and even safety. A regulatory oversight would require developers to provide safety relevant information in a harmonised and systematic way. Regulatory oversight would also be in the interest of producers as approved products or notifications also represent a reassurance for new clients or users. It will be important to carefully balance the risk assessment requirements - otherwise this might be detrimental for the many SME type developers.