

Chapter 10

Microbes in cleaning products: Regulatory experience and challenges for risk assessment

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This chapter: i) provides an overview of the technology, products and applications of the use of micro-organisms in cleaning products; ii) discusses the application of existing legislation; iii) identifies and discusses possible environmental and health risks as well as environmental benefits; and iv) provides recommendations to regulators for further research and policy action.

Introduction

Over recent years, consumer and environmental organisations have become increasingly aware of a novel type of cleaning products containing living micro-organisms as active ingredients (subsequently termed “microbial cleaners”). Given the lack of both general information on microbial cleaners in the public domain and product-specific information from developers, these organisations highlight difficulties in considering these products when providing recommendations to the public and private sector for green procurement. Information is considered to be particularly scarce on the environmental properties, health risks and efficacy of the cleaning products. Furthermore, it is not clear which legal regulations are governing the safety and marketing of these products.

Against this backdrop, this chapter: *i*) provides an overview on the technology, products and applications; *ii*) discusses the application of existing legislation; *iii*) identifies and discusses possible environmental and health risks as well as environmental benefits; and *iv*) provides recommendations to regulators for further research and policy action.

The analysis 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 European Union context with a particular emphasis on Austria, though information on Canada and the United States was also considered.

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.

Rationale of using micro-organisms in cleaning products

The overall rationale for using microbes is similar for all types of products. Living microbes are capable of enzymatically degrading substances associated with dirt, food residues, grease and other objectionable matter (known in cleaning terminology as “soil”) and/or bad odours. Microbial action is aimed at controlling odour and to support the cleaning action of detergents. Producers of microbial cleaners frequently make environmental and efficacy claims.

Some micro-organisms 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 degradation 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 micro-organisms 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 micro-organisms will stay on the treated surface (as spores; many formulations contain spore forming bacteria, e.g. *Bacillus* spp.) and hinder re-colonisation by unwanted microbes.

Products and applications

Microbial cleaners are frequently marketed directly by manufacturers which are in almost all cases SMEs (small and medium enterprises). Most operators are blenders, i.e. they purchase 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. We identified some 30 manufacturers in Australia Austria, Belgium, Canada, Germany, Japan, the Netherlands, Switzerland, the United Kingdom and the United States. 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 (for details see Spök and Klade, 2009).

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, nursing/retirement homes, animal shelters, veterinarian 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 the 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 Micro-organisms (EM®, EM Research Organization Inc.) 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 cleaners are not only applied in all the areas described above but recommended for a much broader range of indoor cleaning applications including tiling, stove, refrigerators, pots and pans, bio-waste containers, 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 admit that microbial cleaners 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

(Haslinger, 2006), 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.

Microbial cleaners in the context of legislation

EU-harmonised legislation

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, EU Directive 2001/95/EC (European Union, 2001) on general product safety 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 workers' health. There is no EU legislation regulating any environmental impacts of these products.

Occupational health

Microbial cleaners are covered by EU Directive 2000/54/EC (European Union, 2000) which regulates the minimum requirements for the protection of workers from risks related to biological agents. Employers (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 micro-organisms used into one of four risk groups based on the pathogenic potential (European Union, 2000: Annex III). Potential allergenic or toxigenic effects (especially the former) are not reflected by the risk group scheme, but these effects also have to be considered (European Union, 2000: Articles 3, 3(d)). 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 microbial 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 EU member countries 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, therefore, out of the scope of the EU Regulation on Detergents (European Commission, 2009). 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.

EU chemical legislation – REACH

All chemical compounds used in microbial cleaners are covered by the new EU chemical legislation REACH. Living micro-organisms 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) (European Chemical Agency, 2012). Manufacturers claim that this view has been confirmed by the Dutch and the Finnish 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 (European Chemicals Bureau, 2006; European Commission, 2008a) whereas the REACH guidance document does not (European Chemical Agency, 2012). 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.

EU biocide legislation

Some microbial cleaners could potentially be considered as biocides, i.e. active substances, intended to destroy or otherwise exert a controlling effect on any harmful organism by chemical or biological means (European Union, 1998: Article 1), which would then be regulated under Directive 98/8/EC (European Union, 1998) for a number of reasons:

- Micro-organisms 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 (European Union, 2007). *B. subtilis* is frequently used in microbial cleaners.
- Drawing on analogies of other borderline cases, it appears possible that the outcompeting of unwanted micro-organisms by other micro-organisms via chemical or biological mechanisms could be considered a biocidal effect if it results from direct action (European Commission, 2003; 2008b). In contrast, a “physical” displacement of unwanted micro-organisms by overgrowing with beneficial micro-organisms or as a consequence of nutrient competition would presumably not be considered as biocidal activity. Manufacturers frequently highlight the latter effects. For many micro-organisms, 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. The question here is then 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 micro-organism 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 the Dutch Food and Consumer Product Safety Authority (VWA, 2004). 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.

United States and Canada

In the United States, the use of naturally occurring microbes in microbial cleaners is not regulated. One exemption is the use of micro-organisms 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 micro-organism is not yet included in the Domestic Substance List (DSL) (see Environment Canada, 2000, 2012a; and Chapter 9). The DSL presently lists some 50 micro-organisms specified by strain and 2 combinations of microbes (“consortia”) (see Environment Canada, 2012b). 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 micro-organisms has undergone the full-fledged assessment of health and environmental risks required for a New Substance Notification which has specific guidance (Environment Canada and Health Canada, 2010). Regulators also do not as yet have information on which of the listed micro-organisms are being used for microbial cleaners (Health Canada, personal communication).

Health and environmental risks

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

Microbial cleaning products differ in the particular combination of micro-organisms used and the particular chemical ingredients, including enzymes (some cleaners also contain enzymes). The combination of micro-organisms and chemicals largely depends on the particular application, but there are also different product designs. In the present 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. 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 micro-organisms 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 in combinations of different *Bacillus* spp. spores instead of using vegetative cells as spores to allow for a longer shelf life, up to one year (for details see Spök and Klade, 2009).

Producers claim that all of their microbes belong to risk group 1 and do not pose any health concerns. Moreover, some of the microbes used in cleaners are generally recognised as safe (GRAS) in food and other processing contexts or as QPS (qualified presumption of safety) in other contexts, indicating that they have a sufficient track record of safe use and handling may be exempted from certain risk assessment requirements. 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 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 improvement.

The 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 cleaners) can produce enterotoxins whereas other strains are not capable of doing so. Differentiation between such strains is also important for the QPS status; toxin-producing strains are explicitly excluded from the QPS status (European Food Safety Authority, 2008). Any erroneous identification could, thus, lead to entirely different results in the hazard assessment. Furthermore, microbial phylogeny and taxonomy have 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 (OECD, 2003).

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).¹ 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 cases, it is done 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 cleaning products

The production of sufficient quantities of micro-organisms for a microbial cleaner is done by standard fermentation technology. Any fermentation process has the potential to result in unwanted micro-organisms 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 (OECD, 2011), and operators of biotechnological processes have therefore established process controls and quality assurance systems aimed at both avoidance (too high levels) of and checking for contaminants.

Information from manufacturers indicated huge variations in process controls and quality assurance. In some cases, this raises 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, 2004). 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 (personal communication). 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 leads to aerosol formation, especially in closed rooms (e.g. toilets). Repeated application on carpets and upholstery can lead to an accumulation of spores and formation of dust-containing spores. Used in daily cleaning, chronic respiratory exposure therefore has to be considered in a health risk assessment. There is evidence in the scientific literature of sensitising properties and of hypersensitivity pneumonitis. In its microbial pesticide programme, the United States Environmental Protection Agency (US EPA) generally recognises that micro-organisms may be respiratory sensitisers. At the present time, in the course of its voluntary partnership environment label programme, 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 (United States Environmental Protection Agency, 2009). 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. Sensitising 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 sensitisation. In the European Union, microbial enzymes are therefore voluntarily considered by industry as respiratory sensitisers and labelled and handled accordingly (R42) (see Federal Environment Agency Austria and Inter-University Research Center for Technology Work and Culture, 2002). 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. 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.

Conclusion

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 as well as 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.

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 in 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 (e.g. YOPI) 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 above issues 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, advocated by Canadian, Dutch and US authorities, could therefore be launched at the EU or international level, for instance at the OECD. A good starting point would be the 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. Until these issues are properly addressed/clarified, a clear-cut recommendation in favour of using microbial cleaners as spray in closed environments or for cleaning carpets and upholstery cannot 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 its shelf life. Very similar to the analysis of the VWA – which was conducted some ten years 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 same may be true for other EU legislations, too. 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 could potentially lead to products which differ markedly in terms of efficacy,

hygiene and even safety. 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.

Prospects for genetically modified micro-organisms in cleaning products

This survey revealed no indication that producers of microbial cleaners are developing genetically modified (GM) micro-organisms tailored for the use in cleaning products. Almost all producers of microbial cleaners are of SME type and it can be assumed that the development and market approval of genetically modified micro-organisms is too costly and the time to market – if successful at all – could easily take a decade. Moreover, the deliberate release of living GM micro-organisms is still lacking consumer/regulatory acceptance. In the related field of bioremediation, there is quite some research ongoing to enhance “cleaning” properties of micro-organisms by using GM techniques (oil spills, etc.) (see Chapter 8). A spill-over to microbes used in cleaning products can be expected once GM micro-organisms are considered more acceptable to be used in the environment.

Note

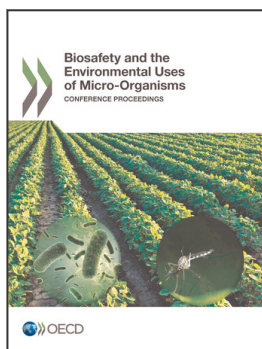
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