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RESULTS FROM THE SURVEY QUESTIONNAIRE ON PERFORMANCE STANDARDS AND RELATED AUTHORIZED LABEL CLAIMS FOR MICROBICIDES USED IN OECD COUNTRIES

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FOREWORD

In 2004, the Task Force on Biocides (TFB) initiated work to develop Test Guidelines and Guidance Documents on antimicrobial efficacy, in order to support the submission of data needed to substantiate a health-related label claim which is a regulatory requirement in many countries.

It was recognised that different terms are used in this context, depending on the OECD country/region. Thus a comparison of the performance standards, authorized label claims and regulations in relation with those performance standards for the microbicide products used in OECD countries was deemed necessary.

To this end, the TFB performed a survey in 2012 and 2015 the results of which are presented in the current report together with recommendations for possible future activities.

This document is published under the responsibility of the Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology.

Summary

Nine European and two North American countries provided responses to an initial questionnaire on performance standards and related authorised label claims for microbicides used in OECD countries. The results of this survey were discussed during the 11th Meeting of the Task force on Biocides (TFB), where recommendations were made for additional questions.

In all of the EU countries responding to the first questionnaire, except for Sweden, such products were regulated and a quantitative method was required to be employed for assessing the efficacy, at least in part. This was still true according to the respondents to the second questionnaire. In the USA, public health-related claims are supported by qualitative data and specific $\log_{10}$ reduction values are not required (although for other areas they are). Although the same basic principle is applied in the regulation of disinfectants (sanitizers) for hard, non-porous surfaces, there are marked differences in the range of organisms that are employed and the size (and especially speed) of effect required to validate their use. In all of the countries that responded to the questionnaire, a combination of suspension tests and surface (coupon-based) tests are employed. In some instances this is required to be supplemented by either tests that simulate practice or data from use in the field.

At the time of the first questionnaire the claim made on a label was regulated by some means or other in 7/11 of the countries that responded. In 9/11 cases this was linked to performance in one or more standard methods. All of the countries that responded to the second questionnaire required such regulation and this was mainly due to the implementation of the Biocidal Products Regulation and the production of unified guidance within the EU.

Although the basic definitions for disinfectants / sanitizers have common elements there are still variations that have a significant impact on their use, especially when linked to specific minimum levels of expected performance. Although now mostly uniform in the EU and Switzerland, in North America the terminology is quite different, although in some ways the terms used are essentially synonymous. It is unlikely that a common set of agreed definitions, linked to specific levels of activity, could be agreed. However, work to bring them closer in scope and at least list the differences and draw whatever comparisons and commonalities can be made would be of great value.

The current OECD hard-surface disinfection tests are carrier-based. As such, they are likely to be more demanding than suspension tests although this will vary depending on the species employed and, to some extent, the nature of the product being tested. Much of the current information about the performance of disinfectants, especially in the EU and Switzerland, is based on the results of suspension tests although in many cases this is linked to performance in use through both simulation tests and historical data. It would be useful therefore to prepare some comparisons of results obtained using the OECD methods and results obtained through some of the key suspension tests and, if possible, data from field simulations. There is at least one coupon-based test used in the EU and the USA that have some common features and offer some similarities to the OECD methods and it may be of value to arrange some testing in parallel to measure the effect of the various parameters on the performance measured.

It is still considered important that this survey be extended in some way to include, ideally, Australia, New Zealand and the Asia Pacific region.

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RESULTS FROM THE SURVEY QUESTIONNAIRE ON PERFORMANCE STANDARDS AND RELATED AUTHORIZED LABEL CLAIMS FOR MICROBICIDES USED IN OECD COUNTRIES

Introduction

1. During a discussion at the 7th meeting of the Task Force on Biocides (TFB) of the results of an initial questionnaire on performance standards used to assess hard surface disinfectants, it was concluded that a Guidance Document that provided a link between such standards and label claims would be useful. Following confirmation of the value of such guidance at the 8th meeting of the TFB and a discussion of the goals of such a document at the 9th meeting, it was concluded that a questionnaire on current practices would be a useful first step. A draft questionnaire was prepared by the OECD secretariat and this was approved at the 10th meeting of the TFB with minor revisions, and was sent to OECD member countries to be completed. Following an analysis of the data generated it was concluded that there were some key pieces of information that had not been collected and that no knowledge of the methods and requirements outside of Europe and North America had been obtained. It was agreed therefore at the 11th meeting of the TFB that a further questionnaire be created to attempt to rectify this. This report presents the results of both the questionnaire originating from the 10th meeting of the TFB (Questionnaire 2) and the questionnaire originating from the 12th meeting (Questionnaire 3, see Annex 1).

2. Responses to Questionnaire 2 were received from 11 member countries and to Questionnaire 3 from 6 member countries. No responses were received for Questionnaire 3 from countries that had not responded to Questionnaire 2. Countries that responded to both questionnaires are highlighted in bold below:

Belgium

Canada (two responses from Health Canada's **Pest Management Regulatory Agency** and Therapeutic Products Directorate)

France

Germany

Hungary

Italy

Netherlands

Slovenia

Sweden

Switzerland

USA

3. From both questionnaires, responses were received for all of the questions but the degree of detail in additional notes varied. Significantly more detail was provided in response to the questions in Questionnaire 3, mainly due to the nature of the questions asked (although in some instances the responses extended to products other than those intended for used on hard surfaces; these have been disregarded). In the responses to Questionnaire 2 the variation in the amount of detail provided appeared to be mainly in proportion to the degree of regulation imposed on hard surface disinfectants in each country. Although Questionnaire 3 generated significantly more detail about the methods employed in the responses, as

anticipated, the distribution of member countries resulted in the acquisition of relatively little new information, or at least of information that was not apparent from knowledge of the general approaches taken with regards the regulation of disinfectants.

Structure of the Questionnaire and Methodology used to Analyse the Responses

4. Both questionnaires were divided into two parts; the first dealt with performance standards used and the second part was related to label claims (principally what terms were employed to define disinfectants, whether claims were regulated and whether these were dependent on certain performance criteria). In the detailed questions, responses were requested based on various end use scenarios covering both private and public areas. These were sub-divided as shown in Table 1 below. The scope of claims was also considered as to whether they were general or specific to certain groups of microorganisms, *i.e.* bacteria (vegetative cells and endospores), fungi, mycobacteria and viruses. Activity against protozoa, algae, cyanobacteria and prions was not included in either survey. The questionnaire can be found in the Annex.

5. As part of the analysis, responses to Questionnaire 2 were tabulated (Tables 2 - 9) and detailed notes, where available, were extracted and are included in the detailed discussion below as well as in information boxes. Any significant changes in response between Questionnaire 2 and 3 are highlighted. Where possible, common approaches and areas where there is significant deviation have been identified, and the implications of the latter on future harmonisation are discussed. The potential impact of the OECD draft quantitative methods for evaluating the activity of microbicides used on hard, non-porous surfaces is also considered.

Table 1: Areas of Use in the Questionnaires

	Area of Use
Private areas	Kitchen
	Bathroom
	Other Household Rooms
Public areas	Human Medicine Area
	Veterinary Area
	Food Area (Catering and Food Industry)
	Industrial Area
	Institution Area
	Workplace (Office)
	Others (*Specify*)

Responses to the Questionnaires

Part 1: Performance Standards

6. The responses to the various questions asked in Questionnaire 2 are summarised in Tables 2 - 9. It can be seen that all of the responding countries except for Sweden (where disinfectants were not at that time regulated, except as medicinal products in special cases; see notes below Table 2a) require a quantitative method to be employed for assessing the efficacy of disinfectants intended for use on non-porous surfaces, at least in part (see USA). In those European countries where disinfectants were regulated, such an assessment was required for bacteria, spores, viruses, mycobacteria and fungi and only data produced using quantitative methods was (and still is) accepted. In most cases both suspension tests and a carrier tests (eg EN 13697) were required and, where not requested previously, will be following full adoption of the Biocidal Products Regulation (BPR): this will apply to all EU member states as all products that make a disinfectant claim require relevant efficacy data as part of their registration process. From the results of the responses to Questionnaire 3 it can be seen that in all of the EU responses, the methods used are as described in EN 14885 and a guidance document is in the process of being drafted with participation from both regulatory authorities and industry. Switzerland follows a very similar approach although will accept data produced using both DGHM and AFNOR standards. Data generated using AOAC methods is not accepted. In the USA, both quantitative and qualitative methods are employed depending on the type of product and the claim made with the exception of products claiming activity against viruses (which require quantitative methods to be used and fungi which require qualitative methods to be used). Data is only required for products that make public health claims. In Canada, hard non-porous surface microbicides are regulated under two different sets of legislation, administered by different branches of Health Canada, and this results in different requirements:

Health Canada's Pest Management Regulatory Agency (PMRA): Controls the regulation of products referred to as sanitizers in Canada - these are regulated as pest control products under the Pest Control Products Act (PCPA).;

Health Canada's Therapeutic Products Directorate (TPD): Controls the regulation of products such as disinfectants and disinfectant/non-food contact sanitizers - regulated as drugs under the Food and Drugs Act.

Table 2a: Response to Question A in Questionnaire 2: Quantitative Assessment Required?

Target	Belgium	Canada		France	Germany	Hungary	Italy	Netherlands	Slovenia	Sweden†	Switzerland*	USA
		PMRA	TPD									
Bacteria	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes	Yes
Virus	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes	Yes
Mycobacteria	Yes	n/a	Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes	Yes
Fungi	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes	No
Spores	Yes	n/a	Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes	Yes

†Currently biocidal disinfectants are exempt from product authorisation. There are disinfectants classified as medical products - see definition for disinfectants on the website of the Swedish Medical Products Agency.
"Disinfectants are primarily classified as biocides or medicinal products. Disinfectants used on patients, e.g. prior to an operation, on damaged skin or diseased animals, are classified as medicinal products. Even other disinfectants used in healthcare, e.g. preoperative hand cleansers, are classified as medicinal products if their prophylactic effect against specific infections is given. Products intended for general disinfection of hands are not classified as medicinal products but instead as biocides. For instance use of the claim 'effective against hepatitis B-virus' is allowed for these products. Marketing products as offering protection against infections caused by the hepatitis B-virus does, however, lead to their classification as a medicinal product."
In the Provisions of the Swedish Work Environment Authority on Microbiological Work Environment Risks, together with General Recommendations on the implementation of the Provisions AFS 2005:1 "Microbiological Work Environment Risks – Infection, Toxigenic Effect, Hypersensitivity" there are qualitative criteria in Section 10, "Decontamination shall be carried out to the extent necessary in order to prevent biological agents causing ill-health. Decontamination shall normally be carried out as early as possible, using agents and methods appropriate to the need. The methods used shall be designed to avoid microbiological air contaminants or other risks to health."
In the General Recommendations (page 56) there is also a semi-quantitative criteria: "Total decontamination cannot be established by measurement but can be described in statistical terms, e.g. that the theoretical likelihood of a living micro-organism being present in a test material is equal to or less than one in 106. To ascertain that a sterilisation has the effect intended, the process has to be validated."

* See http://www.bag.admin.ch/anmeldestelle/13604/13869/13880/14043/index.html?lang=fr

Table 2b: Response to Question A1 in Questionnaire 3: Qualitative Assessment Required?

Target	Belgium	Canada		France	Germany	Hungary	Italy	Netherlands	Slovenia	Sweden	Switzerland	USA†
		PMRA										
Bacteria	No	No		No				No			No	No
Virus	No	No		No				No			No	No
Mycobacteria	No	No		No				No			No	No
Fungi	No	No		No				No			No	Yes
Spores	No	No		No				No			No	No

† Antimicrobial efficacy data is required to be submitted to the USEPA only for antimicrobial products with public health claims. Both quantitative and qualitative methods are available in the US. Their use depends upon the product form (e.g. spray, wipe, liquid, concentrate), type of organism, active ingredient, and efficacy claim (e.g. disinfectant, sanitizer)

7. In Canada, quantitative data from tests such as DIS-TSS 10, ASTM E1153, ASTM 2111 or ASTM 2197 are required for non-food contact surface sanitizers and DIS-TSS 04, AOAC 960.09 or AOAC 955.16 are required for food contact surface sanitizers for bacteria, viruses and fungi but not for mycobacteria and bacterial endospores. This is because sporicidal and mycobactericidal products are regulated as drugs (disinfectants) by Canada's TPD. Quantitative data are required for all groups by TPD.

8. The responses from Questionnaire 2 showed that the methodologies used in the EU and Switzerland were dominated by those described in CEN 14885 (CEN, 2007) and, although not regulated in Sweden at that time, respondents noted that this cascade was often employed by companies marketing disinfectants and that wet wipes, based on ethanol, were validated using EN1276 and EN1650. Switzerland also accepted data produced using DGHM and AFNOR standards but not AOAC methods and this was still the case at the time that Questionnaire 3 was circulated. In the Netherlands, a maximum contact time of 5 minutes was specified for all products although testing to the Phase 2 Step 1 (*i.e.* suspension test) level was considered sufficient. In Germany, either the cascade described in CEN 14885 or in the DGHM standard methods (Gebel et al, 2002) were employed for bacteria, mycobacteria, fungi and spores as a first step. For viruses, the methods described in DVV Leitlinie were used. Where possible, a second tier of testing using more practical tests was employed. For example, in the medical area, DGHM Method 14 was specified and for viruses, the DVV carrier test was used. In both the veterinary and food areas methods from DVG were employed as well as those described in CEN 14885. In general, products were regulated on a regional basis in Germany, often through the use of proscribed lists. This is described in more detail in the information box below. Thus, with the exception of Sweden, a tiered approach was employed in Switzerland and those EU countries that responded, using both quantitative suspension tests and, where available, carrier tests. As noted in the information box below, at the time that Questionnaire 2 was circulated a document intended to provide guidance on this approach was being produced. This is now complete for most of Product Types 1-5 described in the BPR and, as noted above, both suspension tests and carrier tests will be required following full adoption of the approaches described in the guidance document and this will apply to all EU member states. This appears now to be mostly adopted as the responses from the EU state that CEN 14885 defines the tests required for disinfectants for hard surfaces in their countries and the detailed responses are reasonably consistent and appear to reflect the content of the EU guidance document.

Detailed Information Relating to Germany (taken from Questionnaire 2)

Because of German federal legislation, hygiene issues are regulated by the regional authorities (German federal state authorities). In most cases they refer to disinfectant lists for the medical, veterinary and food area published by scientific societies or federal institutes.

The "Association for Applied Hygiene" (VAH, see http://www.vah-online.de) publishes the "VAH List of Disinfectants". Efficacy of the listed disinfectants has been tested according to the "DGHM Standard Methods for Testing Chemical Disinfection Processes" (Gebel et al. (2002) Standardmethoden der DGHM zur Prüfung chemischer Desinfektionsverfahren; mhp-Verlag GmbH, Wiesbaden). The list is a reference for prophylactic disinfection measures in public facilities (medical and other) and, in the event of substantiated medical indications such as infectious diseases at home, also for the private home. Disinfectants used in large-scale/canteen kitchens may follow the testing guidelines of the "German Veterinary Medical Society" (DVG, see http://www.dvg.net/index.php?id=1449, currently German only).

In special cases, i.e. officially ordered disinfection for the containment of human or animal diseases according to the Infection Protection Act (IfSG) or the Epizootic Disease Act (TierSG), the disinfectants used shall be those listed by the "Robert Koch-Institut" (RKI, http://www.rki.de/DE/Home/homepage_node.html) or the DVG (see above), respectively.

The premise for the inclusion of a disinfectant in any of the above mentioned lists is the proof of efficacy in methods that simulate the practical use situation. The data in the questionnaire correspond to the requirements of the corresponding test methods.

However, based on the need for harmonisation of efficacy data requirements and performance standards for disinfectants within the framework of biocidal product authorisation, a working group of European experts (Competent Authority members, industry and other organisations) revised the Appendices to Chapter 7 on disinfectants from the EU Technical Notes for Guidance (TNsG) on Product Evaluation. The document currently focuses on (EU) Product Type (PT) 2 but will be extended to cover the other (EU) PTs in Main Group 1[1]. It was discussed and accepted by the EU Technical Meeting IV/12. Within this document, it is outlined that efficacy data should be generated using internationally (CEN, OECD, etc.) or nationally (VAH/DGHM, DVG, etc.) recognised testing methods employing a tiered approach of quantitative suspension tests followed by practical/carrier tests. Products should meet the performance standards and pass criteria specified in these methods.

[1]In the EU, 23 Product Types are identified, grouped into four Main Groups. Main Group 1 (Disinfectants and general biocidal products) includes 5 Product Types, as follows:
Product-type 1 - Human hygiene biocidal products
Product-type 2 - Private area and public health area disinfectants and other biocidal products
Product-type 3 - Veterinary hygiene biocidal products
Product-type 4 - Food and feed area disinfectants
Product-type 5 - Drinking water disinfectants
For further information, see Annex V of EU Directive 98/8/EC, available at
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:123:0001:0063:EN:PDF

9. In the USA, as noted above, a combination of qualitative dilution step tests as well as quantitative suspension and carrier-based tests are employed, depending on the nature of the intended application and the claim made (further detail is given in the information box below). In Questionnaire 3 it was noted that it is not necessary to perform both a suspension test and a coupon-based test to substantiate a claim. A similar situation exists in Canada; however, data generated through other, scientifically valid tests, such as the CEN 14885 cascade may also be accepted.

Detailed Information Relating to the USA (taken from Questionnaire 2)

The United States predominately uses qualitative test methods (e.g., AOAC Use Dilution method, AOAC Germicidal Spray Products Test) for limited, broad-spectrum and hospital disinfectant label claims. The exceptions are the quantitative methods listed below.

For non-food contact sanitizers against bacteria, the EPA recommends the ASTM Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (E1153). Annual Book of Standards, Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces, Designation E1153. American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA 19428.

For food contact sanitizers against bacteria, the EPA recommends the AOAC International Germicidal and Detergent Sanitizing Action of Disinfectants Test for non-halide chemicals. Official Methods of Analysis of the AOAC International, Official Method 960.09 Germicidal and Detergent Sanitizing Action of Disinfectants. Current edition. AOAC International, Suite 500, 481 North Frederick Avenue, Gaithersburg, MD 20877-2417.

For virus claims, the EPA recommends either the AOAC International Use-Dilution Method, modified for viruses or the ASTM E1053 Test Method for Efficacy of Virucidal Agents Intended for Inanimate Environmental Surfaces. Official Methods of Analysis of the AOAC International, Chapter 6, Disinfectants, Use-Dilution Methods (955.14, 955.15, & 964.02), Current edition. AOAC International, Suite 500, 481 North Frederick Avenue, Gaithersburg, MD 20877-2417. Annual Book of ASTM Standards, Test Method for Efficacy of Virucidal Agents Intended for Inanimate Environmental Surfaces, Designation E1053. American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA 19428, current edition.

For certain sporicidal claims (against *Bacillus anthracis* or *Clostridium difficile*), the Three Step Method or the Quantitative Carrier Test 2 are used. Official Methods of Analysis of the AOAC International, Chapter 6, Disinfectants, Official Method 2008.05 Quantitative Three Step Method (Efficacy of Liquid Sporicides Against Spores of *Bacillus subtilis* on a Hard Non-porous Surface), Current edition. AOAC International, Suite 500, 481 North Frederick Avenue, Gaithersburg, MD 20877-2417. Annual Book of ASTM Standards, Standard Quantitative Carrier Test Method to Evaluate the Bactericidal, Fungicidal, Mycobactericidal, and Sporicidal Potencies of Liquid Chemical Germicides, Designation E 2197. American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA 19428, current edition.

For mycobactericidal label claims, the Quantitative Suspension Test Method is used. Environmental Protection Agency, Data Call-in Notice for Tuberculocidal Effectiveness Data for All Antimicrobial Pesticides with Tuberculocidal Claims (Registration Division, Office of Pesticide Programs, June 13, 1986).

10. It can be seen from the responses in Table 3 below, that at the time that Questionnaire 2 had been circulated there was significant variation in the requirements for data for the different groups of microorganisms dependent on the area in which the disinfectant was to be employed. France had yet to consider veterinary and food area disinfectants, however, the minimum requirement in all countries that responded was for data to be provided against bacteria and in most instances fungi also (in France and the Netherlands this was often reduced to yeasts only), although for private areas activity against fungi was only requested for products used in bathrooms by Italy. In responding to Questionnaire 3, Belgium, Netherlands and France recorded that at least bacteria and yeasts should be employed and Netherlands noted that other organisms should be used when specific claims were made. France required bacteria only for products used in private area bathrooms and other rooms and in veterinary areas and bacteria and yeasts in all others. In all cases for the European respondents to Questionnaire 3, the core species specified for the various standards described within EN 14885, depending on application area, were required. Belgium noted the requirement for the addition of *Salmonella sp* for kitchens and other food areas. In the USA, data against a core set is also required although this does, in general, consist of fewer species. Again the core set varies with the intended application areas and claims against species not in the core set requires

additional testing. In most cases less lots of product and fewer replicates are required when producing data for microorganisms that are not part of the core set for a given product category.

Table 3: Response to Questions B In Questionnaire 2: What Types of Microorganisms Require Performance Standards Concerning the Following Areas of Uses?

Area	Belgium	Canada		France	Germany	Hungary	Italy	Netherlands	Slovenia	Switzerland	USA
		PMRA	TPD								
Kitchen	BF	BFV (MS)†	BFVMS	B‡	*NR*	BF	B	BY‡	BFVMS	BF[x]VMS	BFV
Bathroom	BF	BFV (MS)†	BFVMS	B‡	*NR*	BF	BF	BY‡[D]	BFVMS	BF[x]VMS	BFV
Other Household Rooms	BF	BFV (MS)†	BFVMS	B‡	*NR*	BF	B	BY‡	BFVMS	BF[x]VMS	BFV
Human Medicine Area	BFMV(S)[U]	BFV (MS)†	BFVMS	BY‡	BFVM	BFVMS	BFVMS	BY‡	BFVMS	BF[x]VMS	BFVMS
Veterinary Area	BFV(MS)[U]	BFV (MS)†	BFVMS		BFV	BFVM	BFS	BY‡ (V)*	BFVMS	O	BV
Food Area	BF(VMS)[U]	BFV (MS)†	BFVMS		BFVS	BF	BFS	BY	BFVMS	BF[x]VMS	BV
Industrial Area	‡	BFV (MS)†	BFVMS	BY‡	BFVMS	BF	BFV	BY	BFVM	BF[x]VMS	BFV
Institution Area	‡	BFV (MS)†	BFVMS	BY‡	BFVMS	BF	BFV	BY	BFVM	BF[x]VMS	BFVM
Workplace (Office)	‡	BFV (MS)†	BFVMS	BY‡	BFVM	BF	B	BY		BF[x]VMS	BV
Others (*Specify*)		BFV (MS)† Farms	BFVMS Farms					BY		S Sporicidal	

Key
B = Bacteria, F = Fungi, V = Viruses, M = Mycobacteria, S = Spores, Y = Yeasts. (x = Yeasts only, fungi optional)
NR = Disinfection is not recommended for households in Germany except under specific conditions - see information box above.
† If there was a valid reason for PMRA to look at mycobactericidal or sporicidal claims, a performance standard would be required.
‡ Either the types of organisms claimed on the label or other organisms in addition, when claimed (in France this is based on the European Claims Matrix).
D Fungi only can be employed if the claim is against only fungi that cause discolouration.
* For use in transport vehicles virucidal testing is required (classic swine fever, Aujeski and foot and mouth disease). O = In the event of a disease outbreak
U Under discussion.

11. As might be expected, the requirements for products used in human medicine, veterinary, food, industrial and institutional areas are more demanding in the range of microorganism to be tested against than for those used in domestic settings. In the USA and Canada, activity against viruses was specified for products for private areas as well as public ones however, of the respondents from the EU, this was only required in Slovenia. In the responses to Questionnaire 3 the requirement for additional species appears to be related to the claim made. The basic requirements remain largely unchanged and reflect the content of EU guidance document. Interestingly Switzerland only require data on veterinary products that are to be used following the outbreak of a specific disease and then data relevant to that is required.

12. Irrespective of the types of microorganisms for which data are required, all of the respondents to Questionnaire 2 (bar Sweden, for the reasons discussed earlier) required that, where a quantitative assessment was applied, that a $\log_{10}$ reduction calculation was performed. The required level of performance is shown in Tables 4 – 6 (below) with the mode of application.

13. In Canada, for domestic kitchen applications the size of $\log_{10}$ reduction required is dependent on the surface to be disinfected, with products for food contact surfaces being required to achieve a twofold $\log_{10}$ greater reduction than for other surfaces. In other examples, specifically Hungary, the size of reduction required was stated as method dependent, with tests based on inoculated coupons (*e.g.* EN 13697) requiring an order of magnitude less reduction than suspension tests. Questionnaire 3 confirmed this and this is exemplified in Tables 4a and 4 b. The size of reduction required is, in part, driven by the tests specified in CEN 14885 based on the intended area of use and mode of application. With the exception of the use of fumigants against bacterial spores in the USA, specific $\log_{10}$ reductions based on the mode of application do not appear to be applied and both Canada and the Netherlands stated in their response to Questionnaire 2 that they considered all application methods in their assessments, although the activity required against mycobacteria is described as product dependent in Canada. Most respondents indicate the methods used and these will dictate the species / strains to be employed. As stated, in the EU this is described in detail in the draft guidance for Product Types 1 – 5. In Questionnaire 3, the Netherlands noted that disinfectants with a vapour function required additional testing. Beyond this, only Hungary and the USA described specific species that are of concern. In Hungary, activity against methicillin resistant *Staphylococcus aureus* (MRSA) is quoted as being of importance in the human medicine area and a reduction of five orders of magnitude in EN 1276 (a suspension test) was specified (this is the standard level of performance required). In the USA, activity against, presumably, the endospores of *Clostridium difficile* and *Bacillus anthracis* (or a suitable surrogate) in healthcare and on interior non-porous surfaces is cited. Activity of products applied normally by mop, sponge, cloth, spray, wipe or by fumigation are expected to achieve a six order of magnitude reduction.

14. As with the range of groups of microorganisms considered, there is significant variation in the size of effect required from country to country. However, in general, there is less variation between the performance required between application areas within a country than between countries. Some of this variation, at least within the EU will almost certainly have been eliminated following the creation of the guidance document.

15. One critical factor that was missing from the information gathered by Questionnaire 2 was contact time, as for many formulation types this, along with soiling materials, has a significant impact on the size of effect that can be achieved during a standardised test. In the Netherlands no contact time longer than 5 minutes was accepted at that time. In others, especially those that follow the cascade described in CEN 14885, the contact time used (and soiling material) was dependent on the intended area of use of the disinfectant (*e.g.* for veterinary products a lower temperature and an extended contact time are described). In a number of protocols (*e.g.* some AOAC methods) contact times can be as short as 30 seconds. Information provided by Questionnaire 3 has helped to clarify this for EU (and Switzerland) and North America (especially USA). There is significant uniformity within the EU (and Switzerland) due to both

the requirements of the BPR and the information provided in guidance for Product Types 1 – 5. Many of the protocols followed in the USA are qualitative in nature and, as these are not used in the EU, not relevant comparisons can be made. However, there are a few comparative protocols and the most relevant comparison is summarised in Table 4c. It can be seen that there is a lot of similarity in approach but that the minimum concentration of soiling agent is nearly 70% higher in the US protocol and a significantly larger contact area is specified but the size of effect required is an order of magnitude smaller. In the USA, with the exception of a protocol used for claims against *Clostridium difficile*, 5% animal serum is used as the soiling agent in all quantitative tests that require one. This former protocol employs the 3 component soiling mixture described in the OECD methods and a note states that this is being considered for other standards as well. In the EU, the soiling agent employed is dependent on the application area for which the product is to be employed (multiple areas could be applicable. These are described below. Although the EU guidance mentions the OECD methods, no reference was made to it by any of the respondents from the EU.

Soiling Agents / Concentrations Employed in the EU

PT 1 and 2 For hospitals and health care:

Dirty 3 g/L bovine albumin + 3 ml/L sheep erythrocytes // Clean 0.3 g/L bovine albumin

PT 1 and 2 other uses:

Dirty 3 g/L bovine albumin // Clean 0.3 g/L bovine albumin

PT 3 general hard surface disinfectants, hoof and animal skin disinfection, pre-milking teat disinfection, and eggs in hatcheries:

Dirty 10 g/L bovine albumin + 10 g/L yeast extract // Clean 3 g/L bovine albumin

PT 3 post milking teat disinfection + outer surfaces of milking equipment:

Clean/Dirty 10g/L skimmed milk

PT 4 general:

Dirty 3 g/L bovine albumin // Clean 0.3 g/L bovine albumin

PT 4 milk industry:

Dirty 10g/L skimmed milk

PT 4 breweries:

Dirty 10g/L yeast extract

PT 4 beverage industry:

Dirty 10g/L sucrose

PT 5 general:

Dirty 3 g/L bovine albumin // Clean 0.3 g/L bovine albumin

Table 4a: EU Response to Questions A3 – A5 in Questionnaire 3: Suspension Tests

Type of Microorganism	Species / Strain	Starting Log_{10} cells/ml	Soiling Agent	Concentration(s) g / L	Diluent used for Product	Contact Times(s) Minutes	Number of replicates required
Bacteria	*S. aureus* ATCC 6538 *P. aeruginosa* ATCC 15442 *E. coli* K12 NCTC 10538 *E. hirae* ATCC 10541 *L .pneumophila* NCTC 11192 / ATCC 33152 *P. vulgaris* ATCC 13315	8	*	*	Standard Hardness Water	*	1
Viruses	ECBO ATCC VR-248 Poliovirus type 1, LSc-2ab Adenovirus type 5, strain Adenoid ATCC VR-5 Murine Norovirus, strain S99 Berlin Murine Parvovirus , minute virus if mice, strain Crawford ATCC VR-1346 Bacteriophages P001 DSM 4262 Bacteriophages P008 DSM 10567	7.5 – 8.0	*	*	Standard Hardness Water	*	1
Mycobacteria	*M. avium* ATCC 15769 *M. terrae* ATCC 15755	9	*	*	Standard Hardness Water	*	1
Fungi	*C. albicans* ATCC 10231 *A. brasiliensis* ATCC 16404	7	*	*	Standard Hardness Water	*	1
Spores	*B. subtilis* ATCC 6633 *B. cereus* ATCC 12826 *C. sporogenes* 51 CIP 7 939	6	*	*	Standard Hardness Water	*	1

* Depending on the use area: see EN 14885

Table 4b: EU Response to Questions A3 – A5 in Questionnaire 3: Surface / Coupon-Based Tests

Type of Microorganism	Species / Strain	Starting Log_{10} cells/ml	Soiling Agent	Concentration(s) G / L	Coupon Size cm^2	Volume of Product (mL)	Diluent used for Product	Contact Times(s) Minutes	Number of replicates required
Bacteria	*S. aureus* ATCC 6538 *P. aeruginosa* ATCC 15442 *E. coli* K12 NCTC 10538 *E. hirae* ATCC 10541 *P. vulgaris* ATCC 13315	8	*	*	Diameter 2 cm or 2 cm^2 depending on the standard	0.1 ml or coupon immersed in Petri dish (20 ml of product solution)	Standard Hardness Water	*	1
Viruses									
Mycobacteria									
Fungi	*C. albicans* ATCC 10231 *A. brasiliensis* ATCC 16404	7	*	Depending of the use area : cf EN 14885	Diameter 2 cm	0.1 ml	Standard Hardness Water	*	1
Spores									

- Depending on the use area: see EN 14885

Table 4c: Comparison of Responses to Questions A3 – A5 in Questionnaire 3 between EU and USA for an Example Coupon-Based Test

Country / Region	Bacterial Species / Strain	Starting Log_{10} cells / Carrier	Soiling Agent	Concentration(s) G / L	Coupon Size cm2	Volume of Product (mL)	Diluent used for Product	Contact Times(s) Minutes	Target Reduction Log_{10}	Number of replicates required
EU*	*S. aureus* ATCC 6538 *P. aeruginosa* ATCC 15442 *E. coli* K12 NCTC 10538 *E. hirae* ATCC 10541	6	0.3 or 3.0 g L-1 Bovine Serum Albumin	Depending on area of use / claim but 3 concentrations required (½ nominal, nominal and 2 times nominal).	2 cm diameter Grade 316 stainless steel	0.1 ml per coupon	Standard Hardness Water	5 minutes at 20ºC	4	1 of 1 lot
USA+	S. aureus ATCC 6538 K. pneumoniae ATCC 4352 or E aerogenes ATCC 13048	5.9	5% animal serum	At or below certified limit.	6.45 cm² on a 18.75 cm² glass carrier.	As per use instructions.	As per use instructions.	$\leq$ 5 minutes at 20ºC – 25ºC	3	5 of 3 lots

*EN 13697: 2001 Chemical disinfectants and antiseptics. Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas. Test method and requirements without mechanical action (phase 2/step 2)

+ASTM E1153 Efficacy of Sanitizers Recommended for Inanimate, Hard, Nonporous Non-Food Contact Surfaces.

Table 4d: Response to Questions C2 in Questionnaire 2: What is the Log10 Reduction Required vs the Method of Application? - Private Areas of Use

Area	Species	Belgium	Canada		France	Germany	Hungary	Italy	Netherlands	Slovenia	Switzerland	USA
			PMRA	TPD								
Kitchen	B F M V S	4 Sp 3 Sp	$5^{fc}/3^{o}$ $5^{fc}/3^{o}$ $5^{fc}/3^{o}$	5 5 $4/6^{pd}$ $> 3^{cyto}$ 6	md md md md md	Disinfection is not recommended for households in Germany except under specific conditions	$5^{s}/4^{hs}$ $4^{s}/3^{hs}$	4 Mp 3 Mp	54543	4/3 4/3 4/3 4/3 4/3	As per relevant EN, DGHM and AFNOR test.	5 Mp,Sp,W,Sn,C
Bathroom	B F M V S	43	333	5 5 $4/6^{pd}$ $> 3^{cyto}$ 6	md md md md md		$5^{s}/4^{hs}$ $4^{s}/3^{hs}$	4 Mp 3 Mp	54543	4/3 4/3 4/3 4/3 4/3		3 Mp,Sp,W,Sn,C 3 Mp,Sp,W,Sn,C
Other Rooms	B F M V S	43	333	5 5 $4/6^{pd}$ $> 3^{cyto}$ 6	md md md md md		$5^{s}/4^{hs}$ $4^{s}/3^{hs}$	4 Mp	54543	4/3 4/3 4/3 4/3 4/3		3 Mp,Sp,W,Sn,C 3 Mp,Sp,W,Sn,C

Key

Species B = Bacteria, F = Fungi, V = Viruses, M = Mycobacteria, S = Spores, Y = Yeasts .
fc For food contact surfaces.
pd Product dependent.
o For other surfaces.
cyto Beyond cytotoxicity.
s suspension test.
hs hard surface (coupon-based) test.
md Method dependent.
U under discussion
ad Application dependent

Key to Application Method (Shown on Right Hand Side of Cell)

Mp Mopping
Sp Spraying
W Wiping
Sn Sponge
C Cloth
Fu Fumigant
Vp Vapourised

Table 5: Response to Questions C2 in Questionnaire 2: What is the Log10 Reduction Required vs the Method of Application? - Public Areas of Use

Area	Species	Belgium	Canada		France	Germany	Hungary	Italy	Netherlands	Slovenia	Switzerland	USA
			PMRA	TPD								
Human Medicine Area	B	5^{U}	333	5	md	5 Sp,W	$5^{s}/4^{hs}$	4 Mp,Vp	54543	4/3	As per relevant EN, DGHM and AFNOR test.	
	F	4^{U}		5	md	4	$4^{s}/3^{hs}$	3 Mp,Vp		4/3		
	M	4^{U}		$4/6^{pd}$	md	4	4	4 Mp,Vp		4/3		4 Mp,Sp,W,Sn,C
	V	4^{U}		$> 3^{cyto}$	md	4	4	4 Mp,Vp		4/3		3 Mp,Sp,W,Sn,C
	S	4^{U}		6	md		3	3 Mp,Vp		4/3		6 Mp,Sp,W,Sn,C
Veterinary Area	B	4^{U}	333	5	md	4 W	$5^{s}/4^{hs}$	4 Mp,Vp	54543	4/3		
	F	3^{U}		5	md	3-4	$4^{s}/3^{hs}$	3 Mp,Vp		4/3		
	M			$4/6^{pd}$	md	4	4			4/3		
	V	4^{U}		$> 3^{cyto}$	md	4	4			4/3		3 Mp,Sp,W,Sn,C
	S			6	md	3-4				4/3		
Food Area	B	4^{U}	Exempt	5	md	4 W	$5^{s}/4^{hs}$	4 Mp,Vp	54543	4/3		5 Mp,Sp,W,Sn,C
	F	3^{U}	Exempt	5	md	3	$4^{s}/3^{hs}$	3 Mp,Vp		4/3		
	M		Exempt	$4/6^{pd}$	md					4/3		
	V		Exempt	$> 3^{cyto}$	md	4				4/3		
	S		Exempt	6	md	3		3 Mp,Vp		4/3		
Industrial Area	B		333	5	md	ad	$5^{s}/4^{hs}$	4 Mp,Vp	54543	4/3		3 Mp,Sp,W,Sn,C
	F			5	md	ad	$4^{s}/3^{hs}$	3 Mp,Vp		4/3		
	M			$4/6^{pd}$	md	ad				4/3		
	V			$> 3^{cyto}$	md	ad				4/3		3 Mp,Sp,W,Sn,C
	S			6	md	ad				4/3		
Institution Area	B		333	5	md	ad	$5^{s}/4^{hs}$	4 Mp,Vp	54543	4/3		3 Mp,Sp,W,Sn,C
	F			5	md	ad	$4^{s}/3^{hs}$	3 Mp,Vp		4/3		
	M			$4/6^{pd}$	md	ad				4/3		4 Mp,Sp,W,Sn,C
	V			$> 3^{cyto}$	md	ad				4/3		3 Mp,Sp,W,Sn,C
	S			6	md	ad				4/3		6 Fu
Workplace (Office)	B		333	5	md	ad	$5^{s}/4^{hs}$	4 Mp,Vp	54543	4/3		3 Mp,Sp,W,Sn,C
	F			5	md	ad	$4^{s}/3^{hs}$			4/3		
	M			$4/6^{pd}$	md	ad				4/3		3 Mp,Sp,W,Sn,C
	V			$> 3^{cyto}$	md	ad				4/3		
	S			6	md	ad				4/3		

For Key see Table 4d

Table 6: Response to Questions C2 in Questionnaire 2: What is the Log_{10} Reduction Required *vs* the Method of Application? - Other Areas

Area	Species	Belgium	Canada (Farm)		France	Germany	Hungary	Italy	Netherlands	Slovenia	Switzerland	USA
			PMRA	TPD								
Others (*Specify)*	B F M V S		333	5 5 $4/6^{pd}$ $> 3^{cyto}$ 6					54543		As per relevant EN, DGHM and AFNOR test.	

For Key see Table 4d

16. As with application area, the type of formulation and the way it is applied will have an impact on the performance of a product in practice, especially volume to surface area ratio, the presence of mechanical action and the contact time (thus a product applied by mop will likely present a longer contact time than one applied by wipe or by spray). In general, it can be seen from Table 7, below, that the range of species tested against does not vary with the type of formulation. Exceptions were given by Germany in the responses given to Questionnaire 2, which, at that time, only tested pressurised sprays against spores in a practical procedure under specified conditions. In the USA, such products are only tested against spores in addition to other species if they are a gas or fumigant. This may well be what was intended by the response from Germany but is now likely superseded by the EU guidance. For towelettes and wipes, Hungary stated that they test the impregnating solution rather than the towel and this appears to be the case in general, however, a new standard has been published which may address this and become incorporated into the EU guidance (EN 16615: 2015 06 - Chemical disinfectants and antiseptics - Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4-field test) - Test method and requirements - phase 2, step 2). In a similar way, many products delivered by pressurised spray are tested as the expressed liquid rather than in a manner that simulates use (even when a coupon-based hard surface test is employed). At the time of Questionnaire 2, activity against bacteria and fungi only were required in Italy for products delivered by pump / trigger spray. This probably reflected that the major range of products presented in this manner were designed for the domestic market. Again, the EU guidance may well have altered this situation. Interestingly, data from field or simulation tests were requested at that time for products intended for private use. For whole room fogging the method described in NF 72-281 was required in Switzerland.

Table 7: Response to Question D in Questionnaire 2: What types of formulations are assessed with the test method used in your country?

Target	Belgium	Canada		France‡	Germany	Hungary	Italy	Netherlands	Slovenia	Switzerland	USA
		PMRA	TPD								
Dilutable liquids	BFVMS	BFV (MS)†	BFVMS	BFVMS	BFVM (S)	BFVMS	BFVMS	BFVMS	BFV	BFVMS	BFVMS
Dilutable powders	BFVMS	BFV (MS)†	BFVMS	BFVMS	BFVM (S)	BFVMS	BFVMS	BFVMS	BFV	BFVMS	BFVMS
Ready-to-use	BFVMS	BFV (MS)†	BFVMS	BFVMS	BFVM (S)	BFVMS	BFVMS	BFVMS	BFV	BFVMS	BFVMS
Pressurised non-foaming	BFVMS	BFV (MS)†	BFVMS	BFVMS	S	BFS	BFV	BFVMS	BFV	BFVMS	BFVM*
Pump / trigger sprays	BFVMS	BFV (MS)†	BFVMS	BFVMS	BFVM	BFVMS	BF	BFVMS	BFV	XBFVMS	BFVMS
Towelettes /wipes	BFVMS	BFV (MS)†	BFVMS	BFVMS	BFVM (S)		BV	BFVMS	BFV	XBFVMS	BFVMS

Key
B = Bactericides, F = Fungicides, V = Virucides, M = Mycobactericides, S = Sporicides.
† If there was a valid reason for PMRA to look at mycobactericidal or sporicidal claims, a performance standard would be required.
‡ If efficacy is claimed.
* Except for gaseous or fumigant products for sporicidal claims
X As there are no specific methods available, data from a combination of suspension and surface methods is accepted.

Part 2: Label Claims

Terms and Definitions Used

17. A number of terms and definitions related to microbicidal substances were reported by the countries that responded. The term "disinfectant" is used both in the EU and in the USA and Canada. However, the term "sanitizer" is only used in a formal basis in the USA and Canada. This term is used within industry in the EU and is often used to describe a process that improves the hygiene of an industrial manufacturing process. In contrast, in both the USA and especially in Canada the term carries a specific meaning related to the activity expressed by the product. In many ways the term sanitizer is used in the USA and Canada where the term disinfectant is used in the EU, in as much as they are often associated with a specific level of performance.

18. Within the EU, the definitions presented in CEN 14885 are the most commonly used and, as noted by the Netherlands, their use is often associated with the performance standards listed in CEN 14885. At the time that Questionnaire 2 was circulated, in Slovenia, disinfection appeared to be used slightly more widely and this respondent noted that sterilisation was used for medicinal products. It is not known whether this has changed or not but it is anticipated that the situation is now closer to that in other EU member states. However, in their response to Questionnaire 2 the Netherlands stated that the use of terms such as disinfectant and sanitiser on labels and in claims are not permitted as they are considered to be potentially misleading. In a number of the definitions for the term disinfection, reference is made to the reduction in the number of, or destruction of, pathogenic and potentially pathogenic microorganisms. At the time of Questionnaire 2 in the USA and Belgium this did not include spores. The position in Beligium is now consistent with other EU member states. In both the definitions given in CEN 14885 and in the USA the effect is defined as being irreversible in the sub-divisions of the terms used and in both there is considerable commonality. The biggest differences are in the size and speed of effect that qualifies their use. In Switzerland there is no specific ordinance for label claims.

19. Specific responses are shown in the two information boxes below.

Terms and Definitions Used - USA / Canada (taken from the Questionnaire)

Canada PMRA and TPD:

Non-food contact sanitizer:	An antimicrobial agent that reduces the microorganism population in the inanimate environment by a minimum of 99.9% (3 $\log_{10}$ reduction) in less than 5 minutes, but does not destroy or eliminate all bacteria or other microorganisms.
Food contact sanitizer:	An antimicrobial agent that reduces the microorganism population in the inanimate environment by a minimum of 99.999% (5 $\log_{10}$ reduction) in less than 30 seconds, but does not destroy or eliminate all bacteria or other microorganisms.
Disinfectant:	An antimicrobial agent capable of destroying pathogenic and potentially pathogenic microorganisms on environmental surfaces and inanimate objects. For the purpose of the present guidance, disinfectants also include disinfectant-sanitizer products, i.e., those with both disinfection and sanitization uses.

USA:

Biocide/ Microbicide	means any substance, or mixture of substances, that kills a number of living microorganisms (e.g., virucide--virus, mycobactericide--mycobacteria, algicide--algae; bactericide--bacteria; fungicide--fungi; slimicide--slime-forming microorganisms).
Disinfectant	means a substance, or mixture of substances that destroys or irreversibly inactivates bacteria, fungi and viruses, but not necessarily bacterial spores, in the inanimate environment.
Fungicide	means a substance, or mixture of substances that destroys fungi (including yeasts) and/or fungal spores pathogenic to man or other animals in the inanimate environment.
Mycobactericide	means a substance, or mixture of substances, that destroys or irreversibly inactivates mycobacteria in the inanimate environment.
Sanitizer	means a substance, or mixture of substances, that reduces the bacterial population in the inanimate environment by significant numbers, (e.g., 3 log 10 reduction) or more, but does not destroy or eliminate all bacteria. Sanitizers meeting Public Health Ordinances are used on food contact surfaces and are termed sanitizing rinses.
Sterilant	means a substance, or mixture of substances, that destroys or eliminates all forms of microbial life in the inanimate environment, including all forms of vegetative bacteria, bacterial spores, fungi, fungal spores, and viruses.
Sporicide	means a substance, or mixture of substances, that irreversibly inactivates bacterial spores in the inanimate environment.

Terms and Definitions Used – EU (taken from the Questionnaire)

Belgium:

Disinfectant	Active substance/product that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects.
Sterilizer	Active substance/product that eliminates all pathogenic microorganisms, including bacterial spores, on inanimate objects (with log 6 reduction).

France

Disinfectants match with the EN 14885 definition

Germany

Definitions regarding disinfection according to CEN 14885

Hungary:

Disinfectant:	The process of killing (inactivating) harmful and objectionable bacteria, cysts and other microorganisms (pathogenic) by various agents such as chemicals, heat, ultraviolet light, ultrasonic waves, or radiation.

Italy

Disinfectant: product able to reduce the number of viable microrganism under defined conditions

Netherlands

Terms like disinfectant, sanitizer, etc. cannot be used since they can be misleading through differences in definition.

Slovenia

According to the Directive 98/8/EC we use term disinfection for the biocides activity. Term sterilization is used in case of medicinal products.

Sweden:

In the Provisions of the Swedish Work Environment Authority on Microbiological Work Environment Risks together with General Recommendations on the implementation of the Provisions AFS 2005:1 "Microbiological Work Environment Risks – Infection, Toxigenic Effect, Hypersensitivity" the following relevant definitions are listed:

Decontamination	Treatment to kill, inactivate or reduce the quantity of biological agents so that they will not cause injury. Disinfection Treatment reducing the number of viable biological agents.
Sterilisation	Treatment to achieve the absence of viable biological agents

Regulation of Label Claims

20. It can be seen from Table 8 below that at the time of Questionnaire 2 that, apart from France, Germany and Sweden, of the countries that responded all regulated the claim made on a label by some means or other. With the exception of Slovenia, this was linked to performance in one or more standard methods (see Table 9). In the USA the claim for public health-related claims are supported by qualitative data and specific $\log_{10}$ reduction values are not required. Although the link between claim and performance is not regulated in Canada, it is set through guidelines and policy. In most instances within the EU, the claim is linked to performance in one or more of the standards described in CEN 14885 in a similar manner to the use of specific terms (see *Part 2: Terms and Definitions Used*) and in the guidance document mentioned previously. In Canada the use of specific named organisms on labels is prohibited for sanitisers regulated by PMRA but can be listed along with generic terms for disinfectants and disinfectant / non-food contact sanitisers regulated by TPD. In Germany, the use of generic terms such as bactericidal and virucidal were employed at the time of Questionnaire 2, and in the Netherlands the groups of organisms for which a claim is being made must be listed (more detailed information about label claims in the Netherlands is shown in the information box below). In their response to Questionnaire 3 the Netherlands noted that the label is created by the registration authority (CTGB) and must be used on products. Products that are also obviously intended to kill microorganisms must also be authorised and carry a label. In most other respondents from the EU, specific organisms are not required to be listed (except, at the time of Questionnaire 2, for claims against certain enveloped viruses in Belgium), however, if they are, data must be presented to support the claim based on the use of additional species with an appropriate test from the CEN 14885 cascade. The situation in the USA is similar. Although specific species are not required to be listed, if they are, then data must be provided that supports the claims.

Label Requirements for the Netherlands - Detail (taken from the Questionnaire)
The NL label claim is a legal instruction for use and is as follows:

This product can only be used for the control of (choose one or more of the following organisms groups) bacteria, bacterial spores, mycobacteria, yeast, fungi and viruses, (describe area of use, below some examples for disinfectants)

- in places were food and or drinks are prepared, treated or stored
- in kitchens in hospitals or other health care institutions
- in stables and animal transport vehicles
- in food industry for CIP
- milking equipment
- …

This product is intended for professional /non-professional use only.

This obligatory part is followed by a part named "Directions for use" in which application, dosing, contact time and other recommendations for use (e.g. pre-cleaning or not) should be described.

21. In response to Question A6 in Questionnaire 3 regarding disinfectants based on nano-materials neither the USA nor Canada had any specific provisions. The Netherlands responded that they did but provided no detail as to how this was achieved. Belgium stated that they did not. The respondent from France noted that there was no specific requirement to declare the quantities and uses of such products but that labelling was required to be compliant with regulation 528/2012 (article 69): "the nanomaterials contained in the product, if any, and any specific related risks, and, following each reference to nanomaterials, the word "nano" in brackets". Switzerland has no specific requirements with regards

efficacy but their presence must be declared and their toxicological properties would be assessed separately, presumably to the non-nano form.

22. Claims for other types of disinfectant product, for which no standard method exists (Question A7 in Questionnaire 3) could be supported in the USA by novel protocols provided these were approved by the EPA. None were considered relevant in Canada, Belgium and France. Wipes and sprays as well as certain treated articles were considered problematic in Switzerland and *in-situ* generated substances in the Netherlands. Although the example given was for drinking water a field trial would be requested.

Table 8: Response to Question F & G2 in Questionnaire 2: Is There Any Applicable Regulation on Label Claims and are they Tied to Performance Standards?

Question	Belgium	Canada		France	Germany	Hungary	Italy	Netherlands	Slovenia	Switzerland	USA
		PMRA	TPD								
Label Claim	Yes	Yes	Yes	No	No	Yes	Yes	Yes	No	Yes	Yes
Linked to Standard	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	No	Yes

Table 9: Response to Questions H in Questionnaire 2: For which areas of use does the label claims regulation apply?

Area	Belgium	Canada†		France	Germany	Hungary	Italy	Netherlands	Slovenia	Switzerland	USA
		PMRA	TPD								
Kitchen	Yes	Yes	Yes			Yes		Yes	Yes		Yes
Bathroom	Yes	Yes	Yes			Yes		Yes	Yes		Yes
Other Household Rooms	Yes	Yes	Yes			Yes		Yes	Yes		Yes
Human Medicine Area	Yes	Yes	Yes		Yes	Yes		Yes	Yes		Yes
Veterinary Area	Yes	Yes	Yes		Yes	Yes		Yes	Yes		Yes*
Food Area	Yes	Exempt	Yes‡		Yes	Yes		Yes	Yes		Yes
Industrial Area	Yes	Yes	Yes		Yes[R]	Yes		Yes	Yes		No
Institution Area	Yes	Yes	Yes		Yes[R]	Yes		Yes	Yes		Yes
Workplace (Office)	Yes	Yes	Yes		Yes[R]	Yes		Yes			Yes
Others (*Specify*)		Yes Farms	Yes Farms			Yes		Yes			

Key

* If a public health claim is made.

† sanitizers, disinfectants, and disinfectant/non-food contact sanitizers

‡ Disinfectants and disinfectant/non-food contact sanitizers

R If disinfection is required

Conclusion and Recommendations

23. Although the same basic principle is applied in the regulation of disinfectants (sanitizers) for hard, non-porous surfaces, there are marked differences in the range of organisms that are employed and the size (and especially speed) of effect required to validate their use. In all of the countries that responded to the questionnaire, a combination of suspension tests and surface (coupon-based) tests are employed. In some instances this testing is required to be supplemented by either tests that simulate practice or data from use in the field.

- At present information is still only available for the EU and North America and it is considered important that this be extended in some way to include, ideally, Australia, New Zealand and the Asia Pacific region;

24. The current OECD hard-surface disinfection tests are carrier (coupon)-based. As such, they are likely to be more demanding than suspension tests, although this will vary depending on the species employed and, to some extent, the nature of the product being tested. Much of the current information about the performance of disinfectants, especially in the EU, is based on the results of suspension tests although further data will become available as products are registered within the BPR.

- Therefore, it would still be useful to prepare some comparisons of results obtained using the OECD methods and results obtained through some of the key suspension tests and, if possible, data from field simulations. There is at least one coupon-based test used in the EU and the USA (see Table 4c) that have some common features and offer some similarities to the OECD methods and it may be of value to arrange some testing in parallel to measure the effect of the various parameters on the performance measured. It may be possible to generate some of this from results from the ring tests used to validate the OECD method and from data held by companies and institutions that provided / prepared those test formulations.

25. Although the basic definitions for disinfectants / sanitizers have common elements there are still variations that have a significant impact on their use, especially when linked to specific minimum levels of expected performance. The EU definitions are provided within CEN 14885 and the draft EU guidance on Product Types 1-5. The OECD methods are mentioned in this but no mention was made to them in the response to Questionnaire 3 and the main vehicle for testing and authorisation appears to be CEN 14885. In North America, the terminology is quite different, although in some ways the terms used are essentially synonymous.

- While it is unlikely that a common set of agreed definitions, linked to specific levels of activity, could be agreed, work to bring definitions closer together in scope and at least list the differences and draw comparisons and commonalities would be of great value.

- Allied to this work, it would be worthwhile investigating whether it is possible to list certain additional data that would be required, in addition to that obtained using the draft OECD methods, to facilitate registration of products in multiple countries / regions.

ANNEX 1: SURVEY QUESTIONNAIRE ON PERFORMANCE STANDARDS AND RELATED AUTHORIZED LABEL CLAIMS FOR MICROBICIDES USED IN OECD COUNTRIES

1. Objectives

The primary objective of this questionnaire is to collect information to allow a comparison of the performance standards, authorized label claims and regulations in relation with those performance standards for the microbicide products used in OECD countries. Different terms are used depending of the country/region. The objective of this document is not to develop harmonized test methods as this is already in process [ENV/JM/MONO(2013)11]. The objective of the current questionnaire thus deals with the use of existing test methods, label claims and regulation of hard-surface microbicides.

For example, the claim "kills 99.9% of bacteria" is sometimes used on consumer product labels but does not really fit with the scientific definition of a microbicide product and does not reflect the real efficacy/activity of the product. Moreover, the juxtaposition of this claim may be rejected or accepted depending on countries.

The secondary objective is to help determine whether potential harmonization is desirable and could be proposed for those label claims or for test conditions.

2. Scope

This questionnaire is focused on microbicides used on hard, non-porous surfaces. Substances described as microbicides are defined below. It should be noted that in certain countries, in some cases, substances used on certain medical surfaces are not considered as microbicides but as medicinal products and should therefore be part of this survey too.

The scope of this survey is to determine the required performance standards of microbicides (and biocides used as medicinal products) and default testing conditions (e.g., hard water, soil, contact time *etc.*) as well as their related label claims. There are substances that have bactericidal, virucidal, mycobactericidal, sporicidal or fungicidal activity. The areas and fields of application, the formulations, the spectrum of activity, the recommended method of application (e.g. use concentrations, contact time, temperature etc.) may vary from country to country. The corresponding evaluating methods designed to assess their activity/efficacy may thus vary as well.

3. Definitions

Microbicide: for the purpose of this questionnaire, a microbicide is a biocidal product for use on inanimate surfaces having any level of antimicrobial activity. Different terms apply to the microbicides with different types of activities. For example, the terms "sanitizer", antimicrobial product, or "disinfectant" are used for distinct products in North America, depending on their performance, whereas certain other countries may use the term "sterilizer" or "disinfectant" as well but with other performance criteria underlying.

The **test substance** is a compound or formulation that is under evaluation for its microbicidal activity. It could be a bactericidal substance, a virucidal substance, a mycobacterial substance, a sporicidal or a fungicidal substance.

A **test method** is the method used to evaluate the performance of a test substance in order to assess its activity/efficacy against the microorganisms (usually under laboratory conditions). It may include specific performance criteria depending on the type of microbicide which is tested.

A **bactericidal substance** is a substance that is able to kill/destroy bacteria under certain conditions (contact time, temperature, use concentration).

A **virucidal substance** is a substance that is able to kill/destroy viruses under certain conditions (contact time, temperature, use concentration).

A **mycobactericidal substance** is able to kill/destroy mycobacteria under certain conditions (contact time, temperature, use concentration).

A **fungicidal substance** is able to kill/destroy fungi under certain conditions (contact time, temperature, use concentration).

A **sporicidal substance** is able to kill/destroy bacterial spores under certain conditions (contact time, temperature, use concentration).

Performance standards in the scope of this survey are performance levels of efficacy which the product must meet (*eg* $\log_{10}$ reduction of viable test organism), related to a given test method, used to test the microbicidal activity of a test substance and which may be used for comparative evaluation of products.

Private Areas are considered to include household and other domestic environments as well as private vehicles as well as personal items such as mobile (cell) phones *etc*.

Public Areas are considered to include places of employment, medical and industrial facilities, areas for public entertainment, public transport *etc*, as well as items used in such environments such as medical equipment, catering equipment, computer keyboards *etc*.

Country Name…….
…….....

4. Questionnaire

Please note that:

The questionnaire is focused on hard, non-porous surface microbicides.

The questionnaire addresses five main classes / sub-divisions of microorganisms: bacteria, mycobacteria, viruses, fungi and bacterial spores. If an additional type of microorganism is taken into account (e.g., yeast) question C3 gives you the opportunity to provide this kind of information

Contact details of the person who has answered to the questionnaire (please insert additional pages as required to accommodate multiple respondents):	
Name:	
Organisation:	
Address:	
Email:	
Phone number:	

PART ONE: Performance Standards

Question A1:

In your country, do you require a quantitative method for microbicide efficacy assessment?

Yes / No

If yes, for which type(s) of microorganisms do you require such a quantitative assessment?

Bacteria	**Yes**	**No**
Virus	**Yes**	**No**
Mycobacteria	**Yes**	**No**
Fungi	**Yes**	**No**
Spores	**Yes**	**No**

And what type of quantitative method do you use, *eg*, AOAC QCT-2; CEN 14885 method…, *(please provide us with a reference or a link)*?

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If no, do you require a qualitative efficacy assessment?

If you require a qualitative efficacy assessment, for which type(s) of microorganisms do you require such an assessment?

Yes / No

Bacteria	**Yes**	**No**
Virus	**Yes**	**No**
Mycobacteria	**Yes**	**No**
Fungi	**Yes**	**No**
Spores	**Yes**	**No**

And what type of qualitative method do you use, *eg*, AOAC dilution method…, *(please provide us with a reference or a link)*?

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Question A2:

In your country, do you use both suspension tests and surface / coupon-based tests?

Yes / No

Question A3:

In your country, do the methods specified use a core set of microorganisms (please see also Question B2)?

Yes / No

If yes, please list (along with strain references, if known) in the two table(s) below Question A5.

Question A4:

In your country, do the methods specified employ soiling agents or interfering substances (please see also Question B2)?

Yes / No

If yes, please list and provide the concentration(s) employed.

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Question A5:

In addition to the detail from responses to questions A3 and A4, please provide, in the tables below, information on the starting size (in $\log_{10}$ cells / mL) of the microbial population in the tests (*ie* when combined with soiling agent and 'inoculum') and the volume of product used (mL) for surface / coupon-based tests as well as the size of the coupons employed (cm^2) and the diluent specified in the tables below. Please also describe the replication specified in the test standard (the number of repeat tests and batches to be tested are dealt with in Question C2B).

Question A6:

In your country, do you have specific provisions for nano-based disinfectant products?

Yes / No

If yes, how do these differ from non-nano-based products?

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Question A7:

In your country, are there other types of disinfectant products for which no standard method exists?

Yes / No

If yes, which ones?

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Suspension Tests

Type of Microorganism	**Species / Strain**	**Starting Log_{10} cells/ml**	**Soiling Agent**	**Concentration(s)** **g / L**	**Diluent used for Product**	**Contact Times(s)** **Minutes**	**Number of replicates required** *
Bacteria		Enter a number, Eg 7			Eg Standard Hardness Water		
Viruses							
Mycobacteria							
Fungi							
Spores							

* For example, how many tubes of each dilution must be tested in parallel?

Surface / Coupon-Based Tests

Type of Microorganism	**Species / Strain**	**Starting Log_{10} cells/ml**	**Soiling Agent**	**Concentration(s)** **G / L**	**Coupon Size** **cm^2**	**Volume of Product (mL)**	**Diluent used for Product**	**Contact Times(s)** **Minutes**	**Number of replicates required***
Bacteria		Enter a number, Eg 7		Of soiling agent / interfering substance			Eg Standard Hardness Water		
Viruses									
Mycobacteria									
Fungi									
Spores									

* For example, how many coupons must be tested in parallel?

Question B1:

What types of microorganisms require performance standards concerning the following areas of uses?

*Please fill out with '**B**' for bactericidal, '**F**' for fungicide, '**M**' for mycobactericide, '**V**' for virucide or '**S**' for sporicide.*

Question B2:

Are there either additional (A) or substitute (S) species / strains other than those specified in the answer to question A2 for specific areas of use?
If so, please list those species/strains in the Table below.

	Areas of use	**B1 - Performance Standards required for...**	**B2 - Specific organisms (*ie* if different from the core species listed in A2)**	**B2 Additional (A) or a substitute (S)**
Private Areas	**Kitchen**	*B? F? M? V? S?*		*A? S?*
	Bathroom	*B? F? M? V? S?*		
	Other household rooms	*B? F? M? V? S?*		
Public Areas	**Human medicine area**	*B? F? M? V? S?*		
	Veterinary area	*B? F? M? V? S?*		
	Food area (catering and food industry)	*B? F? M? V? S?*		
	Industrial area	*B? F? M? V? S?*		
	Institution area	*B? F? M? V? S?*		
	Workplace (office)	*B? F? M? V? S?*		
	Others *(specify)*	*B? F? M? V? S?*		

Question C1:

Do you require a $\log_{10}$ reduction calculation as a performance criterion for the test substance?

Yes

If yes, please fill out the following table (question C2)

go to question C2

No

If no, what are the other quantitative criteria required?
(please provide us with references)

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Question C2A:

Please complete the following tables (C2A1-3) with the log_{10} reduction value required (as a number) and contact time (in minutes), temperature (°C), soiling agent required (*eg* Bovine serum albumin / BSA, yeast extract / YE, blood *etc*) and concentration(s) (g / L) depending on the areas of use and type of microorganism. Please indicate whether the test is a suspension test (ST) or a coupon-based. Hard surface test (CT). Please also specify the corresponding mode of application and if there is a maximum contact time please state it.

Abbreviations are: *'**B**' for bacteria, '**F**' for fungi, '**M**' for mycobacteria, '**V**' for virus, '**S**' for spores.*

Please include any other abbreviations you use here (BSA for Bovine serum albumin, YE for yeast extract *etc*)

Additional abbreviations:

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Question C2B:

Do you require the test to be repeated on more than one occasion and / or with more than one batch of a product (please specify)? How is within test, between test and between batch variability accounted for? Are there specifications and limits etc?

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Question C2C:

In your country do you require field / in-use data for any hard surface microbicides?

Yes / No

If yes, how is the type of trial designed?

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Question C2D: In your country can field data be used in place of a standard test?

Yes / No

If yes, please indicate why this might be the case and list and standard methods that are available.

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Question C2A1 – Private Areas of Use

	Areas of use	Microorganisms	Log_{10} Reduction	Contact Time (Minutes) / Temperature (°C)	Soiling Agent	Concentration (g / L in test)	Type of Test Suspension / Coupon	Mode of Application of the Product
Private Areas	**Kitchen**	B	*(eg 5)*	*(eg 5 / 20)*	*Specify type*	*(eg 1.5)*	*ST / CT*	*Specify a mode of application*
		F			*(eg BSA)*			***(e.g., 'mopping, 'vaporising', please specify)***
		M						
		V						
		S						
	Bathroom	B						
		F						
		M						
		V						
		S						
	Other household rooms	B						
		F						
		M						
		V						
		S						
	Personal Items (such as mobile phones, computer keyboards *etc* using wipes and sprays *etc*).	B						
		F						
		M						
		V						
		S						

Question C2A2 – Public Areas of Use

	Areas of use	Microorganisms	Log_{10} Reduction	Contact Time (Minutes) / Temperature (°C)	Soiling Agent	Concentration (g / L in test)	Type of Test Suspension / Coupon	Mode of application
Public Areas	**Human medicine area**	B	*(eg 5)*	*(eg 5 / 20)*	*Specify type (eg BSA)*	*(eg 1.5)*	*ST / CT*	*Specify a mode of application* ***(e.g., 'mopping, 'vaporising', please specify)***
		F						
		M						
		V						
		S						
	Veterinary area	B						
		F						
		M						
		V						
		S						
	Food area (catering and food industry)	B						
		F						
		M						
		V						
		S						
	Industrial area	B						
		F						
		M						
		V						
		S						
	Institution area	B						
		F						
		M						
		V						
		S						
	Workplace (office)	B						
		F						
		M						
		V						
		S						

Question C2A3 – Other Areas of Use

For example, automotive air conditioning system disinfectants, disinfectants for professional items and equipment (see personal items in Private Area table), industrial processes (*eg* pipework, machinery) *etc*.

	Areas of use	**Microorganisms**	**Log_{10}reduction**	**Contact Time (Minutes) / Temperature (°C)**	**Soiling Agent**	**Concentration (g / L in test)**	**Type of Test Suspension / Coupon**	**Mode of Application**
	Others *(specify)*	B	*(eg 5)*	*(eg 5 / 20)*	*Specify type*	*(eg 1.5)*	*ST / CT*	
		F			*(eg BSA)*			
		M						
		V						
		S						

Question C3

Do some particular microorganisms of interest (*eg* a certain strain of bacteria relevant for human health) require a specific log_{10} reduction, contact time, temperature, soiling agent *etc*?

Yes / No

If yes, please specify:

- which microorganism? (please write species/strain) .....
- what log_{10} reduction is required specifically for this strain? (please fill out with a number)? .....
- what temperature
- what contact time (in minutes)?
- which soiling agent (and concentration)
- which mode of application? .....
- which use or area of use (please write a use or an area of use)? .....

Question C4

Are surrogates of pathogenic species / strains permitted to be used to reduce risk to operators (or for other reason – please specify)?

Yes / No

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Question D:

What types of formulations are assessed with the test methods used in your country? *Please fill-out the following table with 'Yes' or 'No' in the blank boxes.*

Formulations	Test Substances				
	Bactericides	**Virucides**	**Mycobactericides**	**Fungicides**	**Sporicides**
Dilutable liquids					
Dilutable powders					
Ready-to-use formulations					
Pressurized non-foaming aerosols					
Pump/trigger spray products					
Towelettes/wipes					

Optional additional comments:

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PART TWO: Label claims and Regulation of Use

Question E1:

In your country, what are the terms commonly used in relation with microbicide substances, and what are the definitions matching with those terms? *(e.g. if you reply 'sterilizer' or 'disinfectant', please give your definition matching with the terms 'sterilizer' or 'disinfectant').*

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Question E2:

Do any of these terms require specific certification or trigger a need for registration?

Yes / No

Please provide a list of such terms and a brief description of the requirements.

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Question F1:

In your country, is there any applicable regulation on label claims for microbicides?

Yes / No

Question F2:

In your country, is the use of hard surface microbicides regulated?

Yes / No

If yes, is regulation based on the claims made on the label, the presence of certain active substances or the intended areas of use (*eg* hospitals)?

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Question G1:

Do you require a list of microorganisms on the label, or are generic terms, *eg* 'bactericide', used?

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Question G2:

Have you tied label claims to performance standards? (*eg*, does the use of the term "disinfectant" require a specific log_{10} reduction, contact time and the use of specific test conditions?)

Yes / No

If yes, which types of organisms are data required for? If there are specific species / strains that must be included, please list.

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Is this true for all products / applications (please give a brief explanation)?

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Is it possible for products with only limited claims to be placed onto the market provided their limitations are given on the label?

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Question G3:

In your country, do you follow a microbe hierarchical approach to labeling?

Yes / No

If yes, please provide some details and examples.

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Question H:

For which areas of use does the label claims regulation and any restrictions apply?

	Areas of use	Label claims regulation Yes/No	Usage Regulated Yes/No
Private Areas	**Kitchen**	*(Please fill out with Yes or No)*	*(Please fill out with Yes or No)*
	Bathroom		
	Other household rooms		
Public areas	**Human medicine area**		
	Veterinary area		
	Food area (catering and food industry)		
	Industrial area		
	Institution area		
	Workplace (office)		
	Others *(specify)*		

Optional additional comments:

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