BUSINESS PLAN

CEN/TC 216
CHEMICAL DISINFECTANTS AND ANTISEPTICS

EXECUTIVE SUMMARY

Business Environment

All chemical products affect the environment and disinfectants are no exception. For that reason, governments, public authorities and regulatory bodies have a significant interest in environmental effects of disinfectants.

In that context, the *Biocidal Products Directive* (Directive 98/8/ECE) lays down rules and procedures for the authorisation of biocidal products in Member States in order to remove barriers to trade among Members States and at the same time to ensure a harmonised high level of protection of men and the environment.
A correct evaluation of their values to society has to take into account a perspective of the benefits offered, the possible environmental and human safety risks and primarily for disinfectants, their efficacy.

Benefits

The standards developed by CEN/TC 216 are to respond if a product has or not an antimicrobial (bactericidal, yeasticidal, fungicidal, mycobactericidal, sporicidal, virucidal) activity.
These standards will allow for the evaluation of the effectiveness of biocides that includes, as required by the Directive 98/8, the antimicrobial activity of an active substance or product.

Priorities

The programme of work of CEN/TC 216 will include phase 1 tests, phase 2 / step 1 tests, phase 2 / step 2 tests and phase 3 tests.
The basic suspension test methods (phase 1 tests) are prepared first, followed by sectorial test methods developed afterwards (phase 2 and phase 3 tests).

1 BUSINESS ENVIRONMENT OF THE CEN/TC

1.1 Description of the Business Environment

The following political, economic, technical, regulatory, legal, societal and/or international dynamics describe the business environment of the industry sector, products, materials, disciplines or practices related to the scope of this CEN/TC, and they may significantly influence how the relevant standards development processes are conducted and the content of the resulting standards.

The *Biocidal Products Directive* (Directive 98/8/ECE of the European Parliament and of the Council concerning the placing of biocidal products on the market) lays down rules and procedures for the authorisation of biocidal products in Member States and for the approval of the active substances of biocidal products at the Community level.
The aim of this Directive is to remove barriers to trade among Members States and at the same time to ensure a harmonised high level of protection of men and the environment with regard to biocidal products. It will provide two lists of active substances with requirements agreed at community level.
In that frame, a correct evaluation of the values of biocidal products to society has to take into account a perspective of the benefits offered, the possible environmental and human safety risks and primarily for disinfectants, their *efficacy*.

In addition, governments, public authorities and regulatory bodies have a significant interest in disinfection for the purpose of regulation, primarily in the areas of healthcare (e.g. medical devices). Among the European standards for disinfectants currently in preparation, six of them (bactericidal activity – phase 2 / step 1 and 2; yeasticidal and/or fungicidal activity – phase 2 / step 1 and 2; mycobactericidal activity – phase 2 / step 1 and 2) are developed under a mandate from the EC and EFTA and supporting "essential requirements" of the *New Approach Directive 93/42 ECE "Medical devices"*. At their publication, they will be "harmonized standards".

If in the frame of the Directive ”Medical Devices”, several WIs are under mandate. In the frame of the “Biocidal products” Directive (BPD) there is no mandate because it is not a new approach directive but the work of the CEN/TC 216 is relevant: the mandated items for WG1 are required for the Medical Devices Directive and the other tests can be used for efficacy under the BPD. For the latter there is no way that field testing can be a requirement of products being used in so many diverse ways and diverse situations.

Interested parties in the standardisation process are therefore all industries at national and international level, both producers and users, public authorities, institutes, laboratories, consumer representatives.

1.2 Quantitative Indicators of the Business Environment

The following list of quantitative indicators describes the business environment in order to provide adequate information to support actions of the CEN/TC.

There are numerous major industries (even if a low percentage of the companies of the sector are multinationals and the other are small and medium companies) with a substantial user interest in disinfection for the purposes of ensuring safety and process control. Harmonised tests for disinfectants and antiseptics are, moreover, needed to prevent barriers to trade.

From the trade viewpoint, the Business Plan of CEN/TC 216 has gone a considerable way to meeting the needs of industry.

The tests that have been developed and those soon to become standards have gone a long way to meet that end.

2 BENEFITS EXPECTED FROM THE WORK OF THE CEN/TC

The standards developed by CEN/TC 216 are to respond if a product has or not an antimicrobial (bactericidal, yeasticidal, fungicidal, mycobactericidal, sporicidal, virucidal) activity. These standards will allow the evaluation of the effectiveness of biocides that includes, as required by the Directive 98/8, the antimicrobial activity of an active substance or product. We see these tests being used as a means of quantifying efficacy both under the Medical Devices Directive and under the Biocidal Products Directive and we agree with the mandated work items and in general with the proposed timing.

We believe the tests as developed are meeting some of the market requirements and that others being developed will meet more. The industrial benefits to be gained from having European Standard Test Methods for Antiseptics and Disinfectants are clearly supported by AISE, the "European Association of Soap and Detergent and Maintenance Product Industries" which represents hundreds of companies engaged in the manufacture of Disinfectants and Antiseptics.
Nevertheless, the tests themselves are of necessity a compromise, because there have been, and are, different cultural approaches by different countries to disinfectant testing. Like all compromises, they are not ideal but can be revised to improve them.

3 PARTICIPATION IN THE CEN/TC

All the CEN national members are entitled to nominate delegates to CEN Technical Committees and experts to Working Groups, ensuring a balance of all interested parties. Participation as observers of recognized European or international organizations is also possible under certain conditions. To participate in the activities of this CEN/TC, please contact the national standards organization in your country.

4 OBJECTIVES OF THE CEN/TC AND STRATEGIES FOR THEIR ACHIEVEMENT

4.1 Defined objectives of the CEN/TC

Directive 98/8/EC concerning the placing of biocidal products on the market, covers a range of biocidal products including the following:

- Human hygiene biocidal products (Working Group 1)
- Veterinary hyginene biocidal products (Working Group 2)
- Food and feed area disinfectants (Working Group 3)
- Private area and public health area disinfectants and other biocidal products (Working Group 3)

The standards developed in the 3 Working Groups of CEN/TC 216 are related to these product types.

Building on the expertise from the various countries it was agreed early on that phased testing was necessary, in particular for disinfection against bacteria and fungi. The objectives of CEN/TC 216 are therefore to elaborate standards, in a sequential mode, to qualify products depending on:

- their activity (bactericidal, yeasticidal, fungicidal, mycobactericidal, sporicidal, virucidal)
- their applications (human medicine, veterinary use, food hygiene and domestic and institutional use)

4.2 Identified strategies to achieve the CEN/TC.s defined objectives

The programme of work of CEN/TC 216 will include phase 1 tests, phase 2 / step 1 tests, phase 2 / step 2 tests and phase 3 tests. These tests will be published as EN standards and are defined as follows:

- phase 1 tests are suspension tests to establish that a product has bactericidal, or fungicidal, or sporicidal activity without regard to specific conditions of intended use (basic activity of the product)
  (the phase 1 tests are devised as a means of distinguishing a product with potential antibacterial or antifungal disinfection or antiseptic properties from those that do not have this potential)

- phase 2 comprises two steps:

  - phase 2 / step 1 tests are suspension tests to establish that a product has bactericidal, or yeasticidal, or fungicidal, or mycobactericidal, or sporicidal, or virucidal activity under laboratory conditions appropriate to its intended use (under conditions representative of practical use)
    (the phase 2/step 1 suspension tests using representative Gram negative and Gram positive strains of bacteria, and a representative yeast and mould for antifungal testing are an improvement on previous tests. Soiling and hard water as well as temperature and time are also taken into consideration and there is the possibility, as well as the obligatory testing, to alter the requirements to suit the actual use situation)

  - phase 2 / step 2 tests are other laboratory tests, e.g. handwash, handrub and surface tests, simulating practical conditions

- phase 3 field tests under practical conditions

In order to specify the relationships between the various tests and to claims and use recommendations, CEN/TC 216 has established a separate EN standard, "Chemical disinfectants and antiseptics – Application of European standards for chemical disinfectants and antiseptics" – the EN 14885:2006.

Finally, in order to avoid overlapping work with existing bodies, liaisons with appropriate other bodies include:

- CEN/TC 102/WG 8 "Sterilizers for medical purposes – Performance requirements and testing for washer-disinfectors" (Res. 4 – Helsinki, 2000)
- IBRG - International Biodeterioration Research Group (Res. 4 – Helsinki, 2000)
- AISE - European Association of Soap and Detergent and Maintenance Product Industries”

4.3 Environmental aspects

CEN/TC 216 is aware of environmental aspects related to the standards developed in the Chemical disinfectants and antiseptics field.

The Committee agreed to incude in the introduction to the revised EN 14885 "Chemical disinfectants and antiseptics – Application of European standards for chemical disinfectants and antiseptics" an

appropriate statement recommending a responsible use of chemical antiseptics and disinfectants (Dec. 6 – Paris 2010).

Environmental aspects are considered for each NWIP and a reference is made to the TC decision 6/2010.

The objective of the introduction of the environmental issues-related statement in EN 14885 is to promote a responsible use of chemical antiseptics and disinfectants by taking into account the inappropriate in-use concentrations and unncecessary use.

5 FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE CEN/TC WORK PROGRAMME

Funding of collaborative trials

These standards dealing with test methods for the evaluation of anti-microbial activity being the result of compromises between the different experiences gained by some European countries through their national standardisation, require some research and validation in order to make sure that they can really serve as reference documents for application of the Directives.

The drafting of the standards is thus dependent from the validation of the test method and from funding being available to undertake the inter-laboratories tests necessary to verify the precision, reproducibility and repeatability of the test methods.

In that context, CEN/TC 216 submitted proposals regarding standards EN 1275, EN 1276 and pr EN 1657 for conducting ring trials on behalf the European Commission DG XII, Science, Research and Development, within the "Standards, Measurements and Testing programme, 5th dedicated call for proposals" (O.J. of 17.12.96). This project was selected by the European Commission (Contract N° SMT4-CT98-2222) to validate the test methods standardised at present and to confirm that some alternatives proposed are interchangeable and yield the same efficacy results.
Regarding the drafting of the standards on instrument disinfectants which are mandated, their round tests, also mandated, were to be conducted prior to the publication of the test methods in order to avoid re-drafting ratified standards. This covered the EN 13727, EN 13624, EN 14348, EN 14561, EN 14562 and EN 14563. Both big ring trials were done and their results were implemented in the different standards