STRATEGIC BUSINESS PLAN – ISO/TC 330

Executive summary

Committee's environment

- The global biocides market size was valued at USD 7.7 billion in 2019 and is expected to expand at a compound annual growth rate (CAGR) of 3.9% from 2020 to 2027. The growth can be attributed to needs regarding Public Health and continuous investments in R&D, development of synergic chemistries for product diversification, innovation, ecological, enhanced performance, and application expansion (Grand View Research[1]).

- The interested parties concerned:
  - Small and Medium Enterprises (SMEs) and more generally all manufacturers
  - Laboratories and testing houses
  - Product users and consumers
  - Hygienists (governments, healthcare professionals, cleanrooms owners and users…) from a number of areas and sectors
  - Regulatory authorities
  - Official and private control bodies (eg: notified bodies…)

- The application sectors include: medical and veterinary areas, aerospace, agriculture, food, hygiene and other industrial fields, institutional and domestic applications.

Benefits expected

- SMEs and manufacturers in general will benefit from ISO standards supporting and guiding their R&D and market assertions.
- Laboratories and testing houses will have clear testing methods to apply to assess the biocidal efficacy and so uses of surfaces.
- Product users will have a clear tool to recognize, compare and identify products that meet their expectations and needs.
- Hygienists (governments, healthcare professionals, cleanrooms owners and users…) from a number of areas and sectors will benefit from these new standards that will clarify and increase their trust in the marketing claims and facilitate product's benchmarks.
- Regulatory authorities will have clears tools for checking and control product claims and the corresponding market.

Main objectives and priorities

To develop:

- standards to evaluate the basic antimicrobial activity of the surfaces and to differentiate the biocidal from the biostatic activity;

[1] Biocides Market Size, Share & Trends Analysis Report By Product (Halogen Compounds, Quaternary Ammonium Compounds), By Application (Paints & Coatings, Water Treatment), By Region, And Segment Forecasts, 2020 - 2027

- standards or technical specifications to evaluate the antimicrobial activity of the surfaces considering efficacy and contact times related to the conditions/areas of use and the ability to maintain performance;
- guidance documents for performing day-to-day surfaces cleaning and disinfection by considering biocidal surfaces.

1.1 ISO technical committees and business planning

The extension of formal business planning to ISO Technical Committees (ISO/TCs) is an important measure which forms part of a major review of business. The aim is to align the ISO work program with expressed business environment needs and trends and to allow ISO/TCs to prioritize among different projects, to identify the benefits expected from the availability of International Standards, and to ensure adequate resources for projects throughout their development.

1.2 International standardization and the role of ISO

The foremost aim of international standardization is to facilitate the exchange of goods and services through the elimination of technical barriers to trade.

Three bodies are responsible for the planning, development and adoption of International Standards: ISO (International Organization for Standardization) is responsible for all sectors excluding Electrotechnical, which is the responsibility of IEC (International Electrotechnical Committee), and most of the Telecommunications Technologies, which are largely the responsibility of ITU (International Telecommunication Union).

ISO is a legal association, the members of which are the National Standards Bodies (NSBs) of some 164 countries (organizations representing social and economic interests at the international level), supported by a Central Secretariat based in Geneva, Switzerland.

The principal deliverable of ISO is the International Standard.

An International Standard embodies the essential principles of global openness and transparency, consensus and technical coherence. These are safeguarded through its development in an ISO Technical Committee (ISO/TC), representative of all interested parties, supported by a public comment phase (the ISO Technical Enquiry). ISO and its Technical Committees are also able to offer the ISO Technical Specification (ISO/TS), the ISO Public Available Specification (ISO/PAS) and the ISO Technical Report (ISO/TR) as solutions to market needs. These ISO products represent lower levels of consensus and have therefore not the same status as an International Standard.

ISO offers also the International Workshop Agreement (IWA) as a deliverable which aims to bridge the gap between the activities of consortia and the formal process of standardization represented by ISO and its national members. An important distinction is that the IWA is developed by ISO workshops and fora, comprising only participants with direct interest, and so it is not accorded the status of an International Standard.

2 Business Environment of the ISO/TC 330

2.1 Description of the Business Environment

The following political, economic, technical, regulatory, legal, social and environmental dynamics describe the business environment of the industry sector, products, materials, disciplines or practices related to the scope of ISO/TC 330, and they may significantly influence how the relevant standards development processes are conducted and the content of the resulting standards:

The worldwide community agrees that infection or biological contamination prevention is still one of its biggest challenges of the century. In fact, the coronavirus crisis highlights the need for urgent action to enhance prevention of pathogen's spreading and vulnerable populations protection. Any improvement will also contribute to reduce social and economic consequences of a pandemic.

Thus, biocidal and antimicrobial surfaces that produce long lasting reduction or inhibition of growth of representative test organisms under defined conditions- now take on a new importance in light of the current pandemic.

On the other hand, based on the various existing products on the market and scientific researches since at least 20 years, biocidal surfaces can play a key role in increasing the control of microbial risks and reducing nosocomial infections which affect hundreds of millions of patients worldwide.

Notwithstanding their potential, biocidal and antimicrobial surfaces remain poorly used mainly because of:

- A lack of confidence in the ability to respond to the claims of these surfaces under the conditions of use
- The potential claims regarding the domain of use
- The impossibility of comparing the products between them because of the too great variability of the test methods, mostly products center.
- The need to prove the compatibility of biocidal and antimicrobial surfaces with the families of disinfectants and cleaning agents to be used on them
- Doubts about the duration of the biocidal and antimicrobial properties
- Doubts regarding the potential release of active compounds with toxicological and ecotoxicological impacts
- The poorly identified balance between Efficiency / Cost

To control and validate the use of biocidal and antimicrobial surfaces and to ensure their reliability and performance, standardization of transversal testing methods to assess biocidal activity of any surfaces is necessary.

Addressing antimicrobial and biocidal efficacies of surfaces independently of the product compounds is innovative and addresses a worldwide need of the market that is to evaluate biocidal efficacy of surfaces in order to reinforce available tools against pathogen microorganisms and reliability on such surfaces efficacy in use conditions.

Various sectors have to ensure contamination control such as:

- The medical sector
  Indeed, according to the World Health Organization (WHO):
- 1 in 10 patients catch an infection while receiving care,
- Effective infection prevention and control reduces healthcare associated infections by at least 30%.

Moreover, the surfaces colonization, including devices, used in biomedical and clinical applications, by undesired microorganisms has become a persistent problem[2]:

- The food sector: food safety management, reduction of chemical preservative agent, heat method vs nutrition, etc.
- The farming sector: reduction of pathogens microorganism, antibiotic resistance
- The pharmaceutical, cosmetics or transportation sectors

International standardized test methods are necessary not only for safety reasons but also for economic ones to facilitate the best choice for each use.

Several studies have underlined (non-exhaustive list[3]) how surface cleaning could vary and overall that its frequency cannot be increased or in line with the contamination rate and the role of biocidal surfaces for continuously reducing microorganism.
Effect of biocidal surfaces in a contamination control context, is alone, not sufficient to ensure safety but in combination with other safety devices/practices (Training, hand hygiene, surfaces disinfection and cleaning, PPE, air contamination control, water…), it is part of a global system that highly reduces risks of infections.

2.2 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 ISO/TC:

[2] Donskey CJ et al. Beyond high-touch surfaces: Portable equipment and floors as potential sources of transmission of health care-associated pathogens, *Am J Infect Control*. 2019

Kramer A. How long do nosocomial pathogens persist on inanimate surfaces? A systematic review *BMC Infect Dis*. 2006

Boyle MA et al. Off the rails': hospital bed rail design, contamination, and the evaluation of their microbial ecology. *J Hosp Infect*. 2019

Russotto V et al. Bacterial contamination of inanimate surfaces and equipment in the intensive care unit. *J Intensive Care*. 2015

[3] Muller MP et al. Antimicrobial surfaces to prevent healthcare-associated infections: a systematic review. *J Hosp Infect*. 2016

B.C Eckstein et al, Reduction of Clostridium Difficile and vancomycin-resistant Enterococcus contamination of environmental surfaces after an intervention to improve cleaning methods (il manque la revue) 2007

Weber DJ et al. The role of the surface environment in healthcare-associated infections. *Curr Opin Infect Dis*. 2013

OJeil et al. Evaluation of antimicrobial surface activity with a newly developed in vitro efficacy test reflective of conditions found in UK hospitals*, J Hosp Infect* 2013:85;274-81.

Vincent M et al. Contact killing and antimicrobial properties of copper. *J Appl Microbiol*. 2018

Francolini I et al. Antifouling and antimicrobial biomaterials: an overview, *APMIS*. 2017

The global biocides market size was valued at USD 7.7 billion in 2019 and is expected to expand at a compound annual growth rate (CAGR) of 3.9% from 2020 to 2027. The growth can be attributed to continuous investments in R&D, development of synergic chemistries for product diversification, innovation, enhanced performance, and application expansion. The demand from each of the application continues to fluctuate depending on the seasonality changes. (Grand View Research[4]).

The market is segmented by Type (Halogen Compounds, Metallic Compounds, Organosulfurs, Organic Acids, Phenolics, and Other Types), Application (Water Treatment, Pharmaceutical and Personal Care, Wood Preservation, Food and Beverage, Paints and Coatings, and Other Applications). The most important sectors by application in terms of market share and revenues are the food and beverage, and the water treatment sectors, followed by the pharmaceutical, and the paints and coatings sectors (Mordor Intelligence[5]). In term of risk analysis, healthcare sector including homecare is acritical area for which biocidal products play a key role for reducing HAI and biological risk in the general population.

Between 2021 and 2026, the biocides market is expected to grow over 5%. This trend is driven by the increasing demand from the food and beverage industry (Mordor Intelligence[6]). However, the demand from each of the application continues to fluctuate depending on the seasonality changes. Developed countries/regions such as the U.S. and the European Union with more stringent regulations and environmental standards are expected to provide lucrative opportunities for environment-friendly or bio-based products (Grand View Research[7]). While, the developing countries, especially in the Middle East and African countries, demand biocidals for water treatment plants. The increasing awareness in the agricultural sector, globally, is likely to act as an opportunity for the biocides market (Mordor Intelligence[8]).

The international market already proposes a wide range of other products claiming to have antimicrobial properties (copper, ceramic, chemical treated surfaces, nanomaterials, silver…).

The current COVID-19 pandemic led to an increase of the market for the general Public Health, especially regarding new concepts as antimicrobial surfaces.

The real added value of ISO/TC 330 is the development of a holistic and global approach for evaluating the effectiveness of any type of biocidal surfaces (porous and non-porous) independently of the product compounds and for also taking into account the needs of different sectors.

[4] Biocides Market Size, Share & Trends Analysis Report By Product (Halogen Compounds, Quaternary Ammonium Compounds), By Application (Paints & Coatings, Water Treatment), By Region, And Segment Forecasts, 2020 - 2027

[5] BIOCIDES MARKET - GROWTH, TRENDS, COVID-19 IMPACT, AND FORECASTS (2021 - 2026)

[6] BIOCIDES MARKET - GROWTH, TRENDS, COVID-19 IMPACT, AND FORECASTS (2021 - 2026)

[7] Biocides Market Size, Share & Trends Analysis Report By Product (Halogen Compounds, Quaternary Ammonium Compounds), By Application (Paints & Coatings, Water Treatment), By Region, And Segment Forecasts, 2020 - 2027

[8] BIOCIDES MARKET - GROWTH, TRENDS, COVID-19 IMPACT, AND FORECASTS (2021 - 2026)

3 Benefits expected from the work of the ISO/TC

Some of the expected benefits from the work of ISO/TC 330 are:

- SMEs, and more generally all manufacturers will benefit from ISO standards supporting and guiding their R&D and market assertions.

- Laboratories and testing houses will have clear testing methods to apply to assess the biocidal efficacy of surfaces.

- Product users will have clear tools to recognize, compare and identify products that meet their expectations and needs.

- Hygienists (governments, healthcare professionals, cleanrooms owners and users…) from a number of areas and sectors will benefit from these new standards that will clarify and increase their trust in the marketing claims and facilitate product's benchmarks.

- Regulatory authorities will have clears tools for checking and control product claims.

Such standards will help and support market evolution and innovation by enhancing global safety especially regards to product claims.

4 Representation and participation in the ISO/TC

4.1 Membership

Please refer to ISO/TC 330 P and O member list

4.2 Analysis of the participation

In order to ensure consistency of ISO standards collection and to take into account needs from various sector and cooperation with technical committees wishing to apply standards for materials or products within their scopes, several liaisons are expected to be needed. The ISO/TC 330 committee has already lunched a call for setting such liaisons among ISO/TCs and external organisations (WHO…).
Participation of as much countries as possible is seeking, but being an O or P members is a decision from each national standardization bodies (NSB), mostly depending of the support of the national industries and competent authorities. Members and NSB will be encouraged to share information about the ongoing ISO work and the possibility to bring new expertise within ISO/TC 330 during conferences and web conferences related to Hygiene, biocidal products, disinfectants, ...
Possibility to contribute by distance exists and will be applied in order to incite countries with low funding on this topic to still be implied on the whole standardization process.

5 Objectives of the ISO/TC and strategies for their achievement

5.1 Defined objectives of the ISO/TC

The objectives of ISO/TC 330 are to develop:

- Standards to evaluate the basic activity of the surfaces and to differentiate the biocidal from the biostatic activity[9] regarding the spectrum of activity (bacteria, mycobacteria, bacterial spores, yeasts, moulds, viruses including bacteriophages)).

- Standards or technical specifications to evaluate the activity of the surfaces in different areas, their related conditions of use and performance retention ability

- Guidance documents for performing day-to-day hygiene with biocidal surfaces

- Standards to evaluate specific antimicrobial activities regarding as an example inhibition of adhesion and biofilm formation.

No transversal methods have been set so far in order to support and clarify end user choices for identifying surfaces with efficacy criteria in correlation with areas risks. Such lack of transversal standards leads to the impossibility to compare efficacy of different type of surfaces with antimicrobial and biocidal properties making those surfaces less used than their potentials for reducing contamination could ensure. The committee will address this need by creating transversal standards with test conditions (eg. ambient conditions), unspecific to materials and close to use conditions.

[9] **biocidal activity of a surface**
capability of a surface to produce a reduction in the number of viable cells or of infectious particles (e.g. inactivation for virus and phages) of representative test organisms under defined conditions

biostatic activity of a surface
capability of a surface to inhibit the growth of viable cells (or replication of infectious particles in the presence of cell hosts) of representative test organisms under defined conditions
Note 1 to entry: The above term cannot be used for claims according to this document.

5.2 Identified strategies to achieve the ISO/TC's defined objectives

Existing standards and referentials will be used for supporting ISO/TC 330 work. This area of standardization is not fully new. Many ISO committee are already focusing on health issues. Moreover, guidance's from EPA, CEN, OCDE and ECHA exist and will be used for setting proposal as consensual in order to minimize the time for developing standards. Prioritization will be fixed by ISO/TC 330 members but proposal for starting with basic evaluation of bactericidal and virucidal efficacies and of course methodology and definition will be made.
Meeting will be planned in accordance with work progress and consultations and work by correspondence will be done in order to keep being productive between each meeting. In order to reach market needs, producing standards should be done in a consensual way and in a reasonable timeframe not excessing 3 years.

6 Factors affecting completion and implementation of the ISO/TC work program

Most possible negative factors would be the validation of test methods which is dependent upon resources being available to validate the approach building consensually. However, participants already involved have experiences and resources of writing efficacy test methods. Moreover, by setting a test method approach that will be used as a basis for all claims will reduce those resource needs.
Finally, this committee has defined and limited the range of testing methods to write. In the future, ISO/TC 330 will be mainly focus on keeping those test methods updated regarding research and market fields and be a central point of resources for biocidal and antimicrobial claims among ISO/TCs committee.

7 Structure, current projects and publications of the ISO/TC

Work program and orientation will be defined by ISO/TC 330 members according ISO rules.

Information on ISO online

- Please refer to ISO online tools that summup and keep updated ISO/TC 330 Scope, work program, published standards, contacts…
  https://www.iso.org/committee/8017922.html

Reference information

Glossary of terms and abbreviations used in ISO/TC Business Plans

General information on the principles of ISO's technical work