

STRATEGIC BUSINESS PLAN ISO/TC 166

Ceramic ware, glassware and glass ceramic ware in contact with food

EXECUTIVE SUMMARY

ISO/TC 166 addresses the behavior and permissible release limits of chemical elements which may be detrimental for human health, such as lead and cadmium from glass and ceramic ware in contact with food. Generally, this includes glass and ceramic ware consumers use for the preparation, cooking, serving and storage of food and beverages but does not include all articles used in food manufacturing industries or those in which food is sold. This is a moderately large industry worldwide that includes manufacturers of earthenware, chinaware, porcelain, as well as numerous cottage industries producing regional ceramic ware for food service. In the glass ware domain the lead crystal glassware industry, a small group of major producers surrounded by smaller specialty lead glass manufacturers, is another major industry segment. Other manufacturing stakeholders are the glass frit, glaze and decorating industries that produce materials for use in glazing and decorating foodware which may contain these potentially hazardous elements.

This technical committee has generated international standards providing an international definition of the test methods and permissible limits of lead and cadmium release from manufactured products. The acceptance of these standards as universal facilitated trade, research and recognition of the properties required of the products manufactured worldwide.

The main objectives of the committee is to maintain and to improve these international standards in order that they reflect modern yet practical methods for the reproducible measurement of lead and cadmium release from ceramic foodware and to define permissible limits for the release of these elements.

According to the needs, the committee may work on other chemical elements which may be detrimental for human health.

1 INTRODUCTION

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 programme 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 163 members: 112 member bodies (full members), 47 correspondent members and 4 subscriber members (organizations representing social and economic interests at the international level), supported by a Central Secretariat based in Geneva, Switzerland.

http://www.iso.org/iso/home/about/iso_members.htm

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

2.1 Description of the Business Environment

The following political, economic, technical, regulatory, legal and social dynamics describe the business environment of the industry sector, products, materials, disciplines or practices

related to the scope of this ISO/TC and they may significantly influence how the relevant standards development processes are conducted and the content of the resulting standards:

The business environment of ISO/TC 166 is dominated by the truly international scope of the industries that produce glass and ceramic ware for food contact and the fact that the export market for any given producer is a major share of his market, not infrequently greater than 50 %. This implies, of course, that much of the product in any given market is imported. This is particularly true in the United States, the largest single market for these products, where imported low value added products arrive from manufacturing sites in Central American and Asia, among others and imported high value products arrive principally from Europe. In Europe, imports come mainly from China (59 %), followed by Turkey (29 %), and the mean value of exports are largely greater than imports (see 2.2). Thus, the high percentage of trade associated with these markets makes the existence of ISO/TC 166 and its standards particularly valuable to the growth and viability of the worldwide manufactures and their markets.

In addition to the physical conveyance of products across political boundaries, the regulatory agencies of the various regions and countries and their policies and regulations provide a myriad of potential constraints to the efficient production and trade of foodware products. The regulations applicable in the USA, for example, are generally defined by the FDA, although the regulations of certain sub-markets, such as California, are defined locally and the meeting of these requirements is critical to successful merchandising of glass and ceramic foodware products.

Similar situations exist in other parts of the world, e.g. in Europe, where studies are in course to redefine regulatory limits for some chemical elements.

Historically, much of the work of the ISO/TC 166 has focused on harmonizing the many local and regional requirements into overarching ISO standards and encouraging the subsequent adoption of the ISO standards in place of trade-restricting local regulations. The harmonization process has largely succeeded, even if a few exceptions still remain.

Technologically, several evolutionary changes in industry have occurred in the past 30 years since the inception of this committee that have resulted in monotonically decreasing rates of heavy metal release from glass and ceramic ware food contact surfaces. In November 1974, an international congress was convened at WHO headquarters in Geneva, Switzerland to present technical data on heavy metal release rates and to discuss the toxicological impact of these exposures. The outcome of this meeting identified the need for international standards and the need for increased understanding of heavy metal release from glass and ceramics. The meeting also triggered the onset of the ISO regulatory process, which developed and matured in this subject area over the following decade.

Two major events evolved from intense research and development efforts in recent decades that have markedly impacted the levels of heavy metals migrating from ceramic and glass food contact surfaces. One event is the dramatically increased understanding of the relationship between ceramic and glass composition and processing and the migration of lead into acid solution. A second event is the advent of lead-free or reduced lead glass and glaze formulations. The use of reduced lead glasses, glazes and decorations has, quite naturally, lead to reduced lead migration levels. Although it is difficult to make a general statement since there are many products and markets, the acceptable level of lead leached from a glass or ceramic foodware product into 4 % acetic acid at 22°C over a 24 h period without stirring has decreased by about one order of magnitude since the early 1970s.

The stakeholder constituency of this committee is broad but predictable. From a market perspective, the major stakeholders are the raw materials suppliers, the ware manufacturers, the distribution chain (wholesalers and retailers) and the consumer. Regulatory groups that focus on consumer and environmental safety are another class of stakeholder

In some parts of the world, consumer organizations and/or retailers are more sensitive and active on files regarding materials intended to come into contact with food: they may be important stakeholders for the field.

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:

The following table on glass tableware gives data only for a specific world area, namely Europe (EU-27), but it shows the importance of trade exchanges of tableware among the different parts of the globe.

	Total production	Exports			Exp./Prod.	Imports			Import/Prod.
	(tons)	(tons)	(k€)	average (€/kg)	(%)	(tons)	(k€)	average (€/kg)	(%)
2006	1 526 000	377 011	1 370	3,63	25%	437 907	725	1,66	29%
2007	1 547 000	389 635	1 370	3,52	25%	474 076	766	1,62	31%
2008	1 440 000	346 602	1 315	3,79	24%	484 324	777	1,61	34%
2009	1 041 000	289 421	975	3,37	28%	407 211	643	1,58	39%
2010	1 016 000	334 124	1 179	3,53	33%	437 422	758	1,73	43%
2011	1 090 000	346 903	1 244	3,58	32%	404 902	694	1,71	37%

In 2011, the number of European manufacturers of domestic glassware is estimated to be below 50, with employees totaling around 18,000 in the sector.

3 BENEFITS EXPECTED FROM THE WORK OF THE ISO/TC

The work of ISO/TC 166 provides numerous benefits to the stakeholders and society in general. The key benefit is the development of standards for testing and for permissible heavy metal release from glass and ceramic foodware surfaces. In the early years of the committee, separate standards were developed for cookware, ceramic ware and glass.

Then, the committee has generated standards that relate to patterns of use. For example, ISO Standard 6486 address the behavior of ceramic ware, glass-ceramic ware and glass dinnerware in contact with food, reflecting the fact that plates and other dinnerware items should behave similarly regardless of the constituent materials. ISO Standard 7086 addresses glass hollowware separately due to specific product characteristics of glass hollowware, principally lead crystal glassware, that differentiate it from those items addressed in ISO 6486.

ISO/TC 166 will continue to improve these standards, and, if needed, to draft others on new subjects, for them to become more accurate and relevant regarding the requirements of society.

This is the condition to make available widely recognized and adopted documents.

Other benefits derived from this committee are the international dialog and occasional international meetings of the working committee that results from the effort to harmonize and normalize the international standards.

The harmonization and normalization of the many local and regional standards that have addressed this topic in the past into a single international standard has had and will continue to have, a major positive effect on reducing testing and certification costs for the many manufacturers serving the varied worldwide market. Clearly, when a single standard exists, assuming it is recognized and adopted by regulatory agencies in participating countries, will have a major influence in reducing marketing costs and promoting trade.

4 REPRESENTATION AND PARTICIPATION IN THE ISO/TC

4.1 Countries/ISO members bodies that are P and O members of the ISO committee

ISO/TC 166 comprises 41 members, divided in 13 P-members (participating) and 23 O-members (observing).

4.2 Analysis of the participation

Participation in ISO/TC 166 is relatively complete and balanced among the countries that participate substantially in the products and markets identified above. The current P members are:

China (SAC)
Czech Republic (UNMZ)
France (AFNOR)
Germany (DIN)
Italy (UNI)
Japan (JISC)
Kenya (KEBS)
Korea, Republic of (KATS)
Netherlands (NEN)
Romania (ASRO)
Thailand (TISI)
Turkey (TSE)
United Kingdom (BSI)

A casual assessment of the most active members in the sector would include, in addition to China and France based co-secretariat, Germany, Italy, United Kingdom and Turkey. These are countries where glass and ceramic products are produced in high volume, often for export. The USA played a major role as Secretary of ISO/TC 166 but relinquished this responsibility in 2007 and its membership in 2012.

The remaining P-members have been active to some degree over the last ten years, with the possible exception of one or two countries.

The observing committee members represent quite a long list, 28 in all : refer to the following link for more details, from literally every part of the world :

http://www.iso.org/iso/home/standards_development/list_of_iso_technical_committees/iso_technical_committee.htm?commid=53606

Overall, this provides a very rich and inclusive committee structure and one that has reached out to all parts of the world for input into methodologies and permissible limit ranges in formulating the international standards.

5 OBJECTIVES OF THE ISO/TC AND STRATEGIES FOR THEIR ACHIEVEMENT

5.1 Defined objectives of the ISO/TC

To maintain existing international standards for the method of testing for the release of lead and cadmium from glass and ceramic foodware and for defining the permissible limits of release and to revise them if needed.

To take into account of progress of technical knowledge e.g. in toxicology, in analytical tools, etc. to improve existing standards and/or to develop relevant new standards ensuring a high level of human health protection with realistic technical, industrial and economic constraints.

To maintain and increase an active participating and observing membership which, along with the working group, provides a forum for international discussion of emerging technological and product/market needs and advances.

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

The ISO committee utilizes a variety of strategies to achieve its objectives. Some of the strategic as well as tactical methods are summarized below.

- The committee makes use of available national, regional or other standards (such as CEN standards via the Vienna Agreement) as source documents on which to base the ISO/TC 166 International Standards.
- Given the increased efficiency of electronic communications [e-mail attachments, FTP, video conferencing] ISO/TC 166 has become increasingly reliant on these methods in place of face to face meetings. Nonetheless, traditional meetings are of unparalleled value for generating open debate and resolving differences during the standards drafting process and are required by this committee during the drafting process.
- The committee has periodically identified the need for pre- and co-normative research to support the ISO committee's work program. This research, which has historically been conducted by universities and independent laboratories, could become a new need to improve standards. Studies should be led on the relations between single extraction values, repeated extractions values, typical consumer patterns of use for tableware and actual consumer intake for chemical elements potentially detrimental for health. Moreover, analytical methods should be up-dated in order them to measure lower contents.
- The structure of ISO/TC 166 is quite simple and efficient. Whereas in prior decades, separate subcommittees existed for various product/market evaluations, the committee has found that plenary discussions of the heavy metal release topics is most efficient since glass, ceramics and other vitreous products share the same mechanisms of release. Thus, general sessions where all topics are discussed in front of all members and

experts had been found to produce the best results for ISO/TC 166. One of the first actions will be to officially close ISO/TC 166/SC 01 "Ceramic ware in contact with food - Release of toxic materials" and to disband ISO/TC 166/WG 01 "Terminology".

6 FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE ISO/TC WORK PROGRAMME

Funding of the secretariat and the committee has, at times, been sub critical. The secretariat currently seeks to increase funding of this effort in a community that is otherwise highly active in technological and regulatory issues.

One of the first requirements to develop efficiently Standards is the availability of technical expertise.

ISO/TC 166 had been inactive for a long time, the "rebuilding" of the "experts network" is an important task to achieve.

The very weak number of replies to systematic reviews in the past years may be interpreted as the loss of links between National Standardization Bodies and the interested parties in their countries: actions to increase their awareness should be led by ISO/TC 166 to ensure that the key people are aware of activity in international standardization. These key people should include regulatory representatives.

Even if the participation may be deemed quite satisfactory, a wide recognition of ISO/TC 166 standards requires the recruitment of more countries to get full international perspectives on the problems and the solutions.

Cooperation with CEN/TC 194 (Utensils in contact with food) should be made closer in order to avoid duplication of works and to reach identical Standards between Europe (where EN are implemented as national Standards in 33 countries) and ISO.

The development of an International Standard in analytical chemistry frequently requires inter-laboratory test not always easy to organize: this could be a brake in the good progress of standardization work for ISO/TC 166.

7 STRUCTURE, CURRENT PROJECTS AND PUBLICATIONS OF THE ISO/TC

The following links provide an overview of the ISO/TC's structure, scopes of the ISO/TCs and any existing subcommittees and information on existing and planned standardization projects, publication of the ISO/TC and its subcommittees.

7.1 [Structure of the ISO committee](#)

7.2 [Current projects of the ISO technical committee and its subcommittees](#)

7.3 [Publications of the ISO technical committee and its subcommittees](#)

Reference information

[*Glossary of terms and abbreviations used in ISO/TC Business Plans*](#)

[*General information on the principles of ISO's technical work*](#)