Glass Specific Guidelines for Conformity Testing as Food Contact Material

(Being developed in the framework of the Cross-Sector Group FCMs & Articles Working Group)

**Scope**

These guidelines cover glass articles which are intended to come into contact with food (FCM, food contact materials). It describes the specificities of glass compared to other selected FCM and provides information for customers on the FCM conformity testing. Recognized test procedures and permissible limits for glass FCM are described and a Supplier’s declaration is proposed. These guidelines, however, exclude food manufacturing equipment, covered by other standards.

**Uses**

The main categories of glassware used as FCM are container glass, tableware and cookware articles. Container glass bottles and jars are mainly used to package and/ or store food and beverages. Some glass containers are used for speciality products such as baby food or diet-specific foods. The primary FCM uses for glass tableware are as plates, tumblers, stemware glasses and storage containers.

The use of flat glass as a FCM is limited. Only a very small proportion of flat glass production, less than 0.5%, is used in products intended to be FCM. This limited number of articles includes cutting boards, decorative serving plates, tables, counter tops and fridge shelves. Given the shape of the articles (flat articles), there is contact with solid food only and not liquids.

There are certain applications in the special glass sector that result in intentional or unintentional use in food contact applications.

In the majority of instances, the flat and special glass manufacturers have no information on the final use of their flat or special glass products at the time of production.

**Material Specific Properties to be considered when testing this class of FCM**

Glass is made from inorganic raw materials. The batch of raw materials is heated up in the furnace to very high temperatures and transformed into glass with an amorphous inorganic molecular structure that is exceptionally stable. Therefore, when glass (made of soda lime silicate, borosilicate, glass ceramic or other formulations) is intended to come into contact with food, it is considered to be inert. That means it is chemically stable and no significant levels of chemical elements from the glass migrate into food or drink.

Therefore, when no significant change in raw materials, glass composition or the production process has occurred, a single test, to determine the level of migration, will be sufficient for an article’s risk assessment.
Brief outline why existing plastic or ceramic testing guidelines seem to be inappropriate for glass

Glass is inorganic, while plastic is mostly an organic material.

With regards to Directive 84/500/EC, the glass industry voluntarily adheres to the food contact rules made for ceramics. However, the ongoing revision of that directive reveals that the measures considered for ceramics do not fit glass, which is a very different material. Although glass and ceramic are inorganic materials, they are produced using different manufacturing processes and have different chemical compositions and physical microstructures:

1) Glass is obtained by melting raw materials at high temperature (about 1500°C), so that they undergo a chemical reaction to form a homogeneous, vitreous material of uniform composition and with an amorphous structure.
2) Ceramic FCMs are heterogeneous materials, typically with a different surface (glaze) from the bulk.
3) Glass is normally manufactured in a continuous melting process, while ceramic materials are normally produced in a batch process.

Need for testing

According to European standard EN 1388-2 (Materials and articles in contact with foodstuffs - Silicate surfaces – Part 2: Determination of the release of lead and cadmium from silicate surfaces other than ceramic ware) (*), testing is not systematically required.

(*) Extract: For homogeneous, i.e. undecorated or unglazed, glassware, such as that made from soda-lime silicate glass or borosilicate glass, and glass ceramic ware intended to come into contact with foodstuffs, no raw materials containing lead and cadmium are used in the manufacture. An exception is crystal glass as defined in the EC Directive for Crystal Glass (69/493/EEC). From soda-lime silicate glass and borosilicate glass any release of lead and cadmium can result from impurities and normally will be below the current detection limits of flame atomic absorption spectrometry (FAAS) for lead and cadmium. For uncoloured, undecorated or unglazed glass articles made from mass-produced soda-lime silicate glass or borosilicate glass, it is not essential to test according to this European Standard.

Test Procedures

There are internationally recognized standard testing methods for testing the suitability of ceramic and glass FCM articles and materials (see below). These test methods are consistent with the European Food and Safety Authority’s (EFSA) published opinion (*) that the evaluation of FCM needs to focus on the testing of the finished article and the manufacturing process used, rather than concentrating on the individual chemical components used to produce the FCM (*).

(*) Extract “Regarding the identification and evaluation of migrating substances, experience has shown that more focus is needed on the finished materials and articles” from https://www.efsa.europa.eu/en/efsajournal/pub/4357

The following are the most used standards:

- ISO 6486-1:1999, Ceramic ware, glass-ceramic ware and glass dinnerware in contact with food -- Release of lead and cadmium -- Part 1: Test method
- ISO 7086-1:2000 Glass hollowware in contact with food -- Release of lead and cadmium -- Part 1:
  Test method, in which the test method corresponds to contact with acetic acid 4%, at 22°C during 24 hours.

- Evaluation of test results

There are internationally recognized standards to evaluate test results of ceramic and glass FCM articles and materials:
- ISO 6486-2:1999 Ceramic ware, glass-ceramic ware and glass dinnerware in contact with food -- Release of lead and cadmium -- Part 2: Permissible limits

<table>
<thead>
<tr>
<th></th>
<th>lead</th>
<th>cadmium</th>
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<tbody>
<tr>
<td>Flatware (“Non-fillable “)</td>
<td>0.8 mg/dm²</td>
<td>0.07 mg/dm²</td>
</tr>
<tr>
<td>Hollowware(&quot;Fillable“)</td>
<td>4.0 mg/l</td>
<td>0.3 mg/l</td>
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➢ The standards do not apply to flat glass where the flat glass manufacturers have no influence over the final use of the product and whether it is used to make a food contact material.
➢ These standards are currently under revision by ISO/TC 166

- Existing requirements

In some EU Member States, requirements with limit values for glass FCM have been defined. The following list gives some examples and is by no means exhaustive.

France has developed guidance for inorganic materials in order to apply the EU FCM framework regulation 1935/2004 (http://www.economie.gouv.fr/dgccrf/materiaux-inorganiques-hors-metaux-et-alliages). For the testing of glass FCM this document refers to the test method of the ISO-standards mentioned in the chapter ‘Test Procedures’.
For lead (Pb) and cadmium (Cd) the limit values of the ISO-standard are applied. Additionally, the following limits for hexavalent chromium (Cr(VI)) are applied:
- Fillable products: 0.03 mg/ l
- Non-fillable products: 0.005 mg/dm²;
- Lip/ rim area: 0.015 mg/ article.

Furthermore, in the revision of the document in 2016, testing of aluminium (Al), cobalt (Co) and arsenic (As) has been introduced and the following specific release limit values apply:
- 1 mg/l for Al
- 0.02 mg/l for Co
- Below detection limit (0.002 mg/l) for As
For reusable articles (e.g. drinking glasses) testing of the third extraction is conducted on four samples for the above-mentioned metals. In between the extractions, the FCM is rinsed with distilled water. If the results of all four samples are below the limit value, or if no more than one result is above the limit value, but without exceeding 50% of the limit value, the article is considered as conforming to the above-mentioned French guide.

Italy

Ministerial Decree of 21 March 1973 (and its 45 updates) “Disciplina igienica degli imballaggi, recipienti, utensili, destinati a venire in contatto con le sostanze alimentari o con sostanze d'uso personale” establishes test conditions for global migration with the following simulants and temperatures according to the type of glass and its application:

- Glass category A: soda lime glass or borosilicate, colourless or coloured, for use as FCM (including sterilization: contact with distilled water at 120°C for 30 minutes)
- Glass category B: soda lime glass even opaque (opal glass, flint and coloured) for use as FCM at temperatures not above 80°C: contact with distilled water at 80 °C for 2 hours

There are two limit values for the global migration, in order to take into consideration the volume of the containers:
- 8 mg/dm² for containers with a capacity less than 500 ml
- 50 mg/kg for containers with a capacity greater than 500 ml

In case of repeated use, the contact procedure has to be performed three times in total (with two intermediate rinses) and the result of the third contact has to be compliant with the above-mentioned limit value.

Special migration

For a third glass category C, drink ware made of lead glass (crystal glass) and intended for repeated short time uses, there is a specific requirement for lead:
- test procedure: at 40°C for 24 h with acetic acid at 3 %
- The migration will be determined after the third contact (with two intermediate rinses).
- specific migration limit: 0.3 ppm Pb

According to another Italian Regulation (Legislative Decree No. 108 implementing Directive No. 89/109/EEC on materials and tools intended to come into contact with food), it is not allowed to produce, sell or use materials and objects intended to come into contact with food that contain, in their composition, more than three centigrams of arsenic (As) per 100 grams of material.

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1 Italian Ministerial Decree of 21 March 1973: “Hygiene requirements of packages, containers and tools intended to come into contact with food or substances for personal use”
Suppliers declaration

These guidelines propose a template to be used as a Supplier’s declaration. The written declaration should contain the following information:
- The identity and address of the company which manufactures the finished glass article and of the importer who imports it into the European Union;
- The identity of the glass article;
- The date of the declaration;
- The confirmation that the article meets relevant requirements in this guideline.

The written declaration shall permit an easy identification of the article for which it is issued and shall be renewed, when substantial changes in the production process bring about changes in the results of the tests mentioned in these guidelines.

Example of Supplier’s declaration

Supplier’s declaration for materials made from glass intended to come into contact with food

Name and address of the issuer;

if different from above
Name and complete postal address of the manufacturer or importer;

Date:

Hereby we declare that the article complies with the general conditions set in the Glass Specific Guidelines for Conformity Testing as Food Contact Material “(Final version on 7 March 2017) as developed by Glass Alliance Europe (GAE) - Food Contact Material Working Group.

Optional

We also declare that the above-mentioned article complies also with the following national requirements also reviewed in the same GAE guideline:
- France
- Italy