

# **INTERNATIONAL CRYSTAL FEDERATION**

## **ISO STANDARDS COMPLIANCE AND CONSUMER COMMITMENT PROGRAM**

### **0 - INTRODUCTION**

This program is the commitment by members of the International Crystal Federation (“ICF”) to compliance with the International Organization for Standardisation’s (“ISO’s”) standards for lead release, and to providing consumers with information relative to the first use of lead crystal storage vessels. Each company will implement the program to its own operation with the same thoroughness and commitment.

### **1 - SCOPE AND FIELD OF APPLICATION**

#### **1.1    SCOPE**

This program is intended for use by manufacturers and distributors of lead crystal who wish to demonstrate their capability to control the processes that determine the acceptability of their products.

The requirements specified in this program are aimed primarily at preventing and detecting any nonconformity relating to lead release during design and production and implementing the means to prevent its recurrence.

Additionally, the program addresses the labeling of lead crystal storage vessels with regard to treatment prior to first use.

#### **1.2    FIELD OF APPLICATION**

This program is applicable in those situations where confidence in product conformance can be attained by adequate demonstration of the manufacturer's or distributor's capabilities in design and production/sourcing.

### **2 - REFERENCES**

- |                 |   |   |
|-----------------|---|---|
| ISO 2859-1:1988 | - | Random sampling method  |
| 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 6486-2:1999 | - | Ceramic ware, glass-ceramic ware and glass dinnerware in contact with food – Release of lead and cadmium – Part 2: Permissible limits |

ISO 7086-1:2000	-	Glass hollowware in contact with food: Release of lead and cadmium – Part 1: Test method
ISO 7086-2:2000	-	Glass hollowware in contact with food: Release of lead and cadmium – Part 2: Permissible limits
<i>Juran's Quality Handbook</i>	-	Joseph M. Juran and Joseph A. De Feo co-editors (6 <sup>th</sup> edition, 2010, McGraw-Hill)

### **3 - DEFINITIONS**

Flatware: Articles which have an internal depth as measured from the lowest point to the horizontal plane passing through the upper rim that does not exceed 25 mm.

Hollowware: Articles which have an internal depth measured from the lowest point to the horizontal plane passing through the upper rim greater than 25 mm.

### **4 - SYSTEM REQUIREMENTS**

#### **4.1 MANAGEMENT RESPONSIBILITY**

##### **4.1.1 POLICY STATEMENT**

Each company will have a clear policy statement. The statement will identify and authorize the actions necessary to implement the commitment to compliance with the ISO lead release limits so as to give assurance to the FDA and customer. It shall state that all material and processes will be detailed systematically.

Individual manufacturers and distributors will determine the most appropriate application according to their particular circumstances and operations.

##### **4.1.2 ORGANIZATION**

The responsibility, authority and the interrelation of all personnel who manage or perform and verify work affecting lead release shall be defined.

The company shall provide adequate resources and assign trained personnel for verification activities.

#### **4.2 DESIGN**

The manufacturer/distributor shall establish and maintain procedures to control and verify the design of the product in order to ensure that the specified requirements are met.

Design control standards shall be adopted and applied for all new shapes and revisions of existing shapes. Normal manufacturing tolerances will be taken into account in setting design control standards to ensure they can be met with sufficient confidence.

The company shall establish and maintain procedures for the identification, documentation and appropriate review and approval of all changes and modifications.

#### **4.3 MATERIALS AND SUPPLIERS**

All raw materials shall be purchased to an agreed specification. Purchasing documents shall contain data clearly describing the material ordered, including, where applicable:

- \* The type, class, style, grade or other precise identification
- \* The title, number and issue of any International Standard to be applied to the material

All raw materials supplied should be in accordance with those ordered. Where applicable, the supplier will be required to supply evidence of conformity.

#### **4.4 PROCESS CONTROL**

The manufacturer/distributor shall identify and plan all aspects of the production process that directly affect lead release and ensure that these processes are carried out under controlled conditions. These processes shall be validated by establishing documented evidence that provides a high degree of assurance that a specific process shall consistently produce a product meeting its predetermined specifications and quality characteristic. Controlled conditions shall include the following.

- a) Use of suitable production equipment, suitable working environment, compliance with reference standards/codes of practice.
- b) Monitoring and control of appropriate process and product characteristics during production, i.e.

Process Characteristics – A system of measurement and recording of all major process variables shall be established. In the case of furnaces, the process control parameters of founding and working stages, such as temperatures and times, shall be monitored and controlled to ensure compliance with standards for heavy metal release.

Product Characteristics – All products shall comply with applicable ISO lead release limits, as follows:

<u>Category</u>	<u>Limit</u>	<u>ISO Standard</u>
Flatware	0.8 mg/dm <sup>2</sup>	ISO 6486-2:1999
Small hollowware of less than 600 ml in volume (including tumblers and stemware)	1.50 mg/l	ISO 7086-2:2000
Large hollowware of between 600 ml and 3 liters in volume	0.75 mg/l	ISO 7086-2:2000
Storage hollowware with a volume of 3 liters or greater	0.5 mg/l	ISO 7086-2:2000

- c) The approval of processes and equipment, as appropriate.

## **4.5 INSPECTION AND TESTING**

### **4.5.1 RECEIVING INSPECTION**

The manufacturer/distributor shall ensure that incoming product/materials are not used or processed until they have been inspected or otherwise verified as conforming to specified requirements in full, and in use under clearly specified conditions. Batches shall be sampled as supplied, for all raw materials used in the manufacture of glass prior to melting.

### **4.5.2 IN-PROCESS INSPECTION AND TESTING**

The manufacturer/distributor shall:

- a) Inspect, test and identify product as required by its own documented procedures. These procedures shall include the items to be sampled (normally worst case), the number and frequency of samples, and the number to be tested. Test methods shall be clearly specified. The application of different test methods shall be specified by reference to their application. Individual test results shall be compared with the design standards, any predicted values and the relevant ISO standards. In addition, sufficient test results shall be taken to record the true variability determined.
- b) Establish product conformance to the relevant ISO standards for heavy metal release.

- c) Apply statistical process control or other techniques, as appropriate. All test articles shall be randomly selected using any generally accepted random sampling method such as ISO 2859-1:1988 or any random method described in the *Juran's Quality Handbook*, Joseph M. Juran and Joseph A. DeFeo co-editors (6th edition 2010), Chapter 6.
- d) Hold product until the required inspections and tests have been completed or necessary reports have been received and verified.

#### **4.5.3 INSPECTION AND TEST RECORDS**

The manufacturer/distributor shall establish and maintain records, relevant to compliance with the applicable ISO standards, which give evidence that the product/material has passed inspection and/or test.

These shall be retained for a minimum of three years.

#### **4.6 INSPECTION, MEASURING AND TEST EQUIPMENT**

Companies shall control, calibrate and maintain inspection, measuring and test equipment, whether owned by the company, on loan, or provided by the purchaser, to demonstrate the conformance of product to the specified requirements. Equipment shall be used in a manner that ensures that measurement uncertainty is known and is consistent with the required measurement capability.

Records of the necessary maintenance and calibration procedures for the above equipment shall be kept.

#### **4.7 CONTROL OF NON-CONFORMING/SUSPECT PRODUCT MATERIAL**

The manufacturer/distributor shall establish and maintain procedures to ensure that product/material that does not conform to specified requirements (or is suspect) is prevented from inadvertent use. Control shall provide identification, documentation, evaluation, segregation (when practical) and disposition of non-conforming product/material.

This product/material shall not be distributed until any further actions or testing has been completed.

## **4.8 CORRECTIVE ACTION**

The manufacturer/distributor shall implement and record changes in procedures resulting from corrective actions.

## **5 - LABELING REQUIREMENTS**

### **5.1 SCOPE**

The labeling requirements set forth in ¶ 5.2 shall apply to all lead crystal hollowware vessels intended for long-term storage of food or beverage. In general, this means any hollowware item with a stopper or other closure, such as a stoppered decanter or an oil and vinegar cruet. Members are also encouraged, however, to apply the label described in ¶ 5.2 to other lead crystal storage vessels, including crystal pitchers and uncovered decanters or carafes.

### **5.2 FACTORY/DISTRIBUTOR REQUIREMENTS**

All ICF members producing or distributing decanters or other “stoppered” lead crystal storage vessels shall affix to the item either a pressure-sensitive sticker or a hangtag containing the following short message in one or more languages appropriate to the market in which the product is to be sold:

**Prior to first use, please fill with 50/50 solution of vinegar  
and water and let stand overnight. Rinse and dry.**