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PUBLIC HEALTH COMMITTEE

COMMITTEE OF EXPERTS ON MATERIALS COMING INTO CONTACT WITH FOOD

POLICY STATEMENT CONCERNING

LEAD LEACHING FROM GLASS TABLEWARE INTO FOODSTUFFS

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NOTE TO THE READER

The Guidelines for lead leaching from glass tableware into foodstuffs are part of the Policy statements on food contact materials.

Guidelines are technical documents and have no legal binding character.

They have to be considered as requirements to be taken into account as models for the implementation of national policies.

They lay down technical and scientific specifications for the manufacture of food contact materials and articles.

If necessary they are amended in the light of technical or scientific developments of manufacturing processes and techniques of food contact materials and articles.

The document is available on the Internet website of the Partial Agreement Division in the Social and Public Health Field:

www.coe.int/soc-sp

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GUIDELINES FOR LEAD LEACHING FROM GLASS TABLEWARE INTO FOODSTUFFS

1. Introduction

1.1. Lead leaching from glass hollowware is regulated by several national legislations and international standards [1] [14] [15] [16] [17] [18] that specify similar test procedures and permissible limits.

1.2. As these standards are mostly derived from ceramics, limits are generally set for both lead and cadmium.

2. Field of application

2.1. These Guidelines apply to glass tableware made from lead-bearing glass. The commercial lead-bearing glass has a PbO content ranging from 6% up to 32% w/w.

2.2. They do not take into consideration the release of cadmium because the presence of cadmium in lead-bearing glass is exclusively due to the minimum presence of impurities in the raw materials. The concentration of cadmium in glass and therefore its migration is considered negligible.

2.3. They do not apply to ceramics, glass-ceramic ware, either decorated or undecorated, and to decorated glassware.

3. Aim of the Guidelines

3.1. The aim of these Guidelines is to set out and specify:

- Accepted principles for lead leaching from glass hollowware and flatware;
- Results from various researches concerning leaching and lead intake;
- Test methods and admissible limits for the migration of lead from glass hollowware and flatware.

4. Terminology

4.1. The various categories of lead glass used for tableware intended to come into contact with food and covered by the present Guidelines are specified in the Directive EEC 69/493 and defined as follows:

- Crystalline: silicate glass containing zinc oxide, barium oxide, lead oxide and potassium oxide; one of these oxides or the sum of all the oxides have to be 10% or more;
- Lead crystal: silicate glass containing 24% or more of lead oxide;
- Full lead crystal: silicate glass containing 30% or more of lead oxide.

4.2. Other terms used in the Guidelines are defined as follows:

- Tableware: glass articles that are intended to be used in contact with foodstuffs for a short time. Storage and cooking are excluded;

- Hollowware: tableware having an internal depth greater than 25 mm., measured from the lowest point to the horizontal plane passing through the point of overflow;
- Small hollowware: hollowware with a capacity of less than 600 ml;
- Large hollowware: hollowware with a capacity between 600 ml and 3 l;
- Very large hollowware: hollowware with a capacity of 3 l or greater*;
- Flatware : tableware whose internal depth, measured from the lowest point to the horizontal plane passing through the upper rim, does not exceed 25 mm.

5. Lead leaching from glass hollowware

5.1. The extent of migration depends on various parameters: the type of extractant, the contact time, the glass composition, the contact temperature, the ratio between the contact surface and the volume of extracting liquid, the physical-chemical condition of the surface in contact with the liquid.

5.2. The first contact between beverage and glassware causes in principle lead release, which is much higher than that observed during the following contacts. [2,3,4]

5.3. Since such a high release occurs only at the very first contact, the corresponding lead intake can be neglected when performing the overall evaluation of the phenomenon. This approach is also justified by the instructions, given to consumers by the major manufacturers, recommending to wash the products before being used. Such a simple and common operation reduces lead leaching during the first contact.

5.4. It is known that when glassware is tested applying a series of cycles, each one consisting of a contact period and a washing period and a standstill period, lead release decreases when the number of contacts increases, reaching values much lower than those observed after the first contact. [3,5,6,7,8,10]

5.5. For repeated contacts of 30', the following relation between lead concentration and contact number applies: [3]

$$LR = a + b/L^2$$

where:

(LR) = lead concentration in the extractant
(L) = contact number
(a) = constant depending on glass composition
(b) = constant depending on the characteristics of the surface layer

5.6. Data are available about lead leaching behaviour of lead crystal articles according to a cyclic test protocol, where each cycle was made from the following phases: [4,10]

- Consumption of real beverages in a total time equal to 30';
- Washing of articles;
- Drying and storage of articles for 7 days;
- Refilling and restart of the cycle (new contact).

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* The definition of 'very large hollowware' corresponds to the category 'storage' as defined by ISO 7086 Ed. 2000

5.6.1. The tested products showed that, after the 4th contact, the increase in lead concentration in beverages (wine and acidic soft drink) stabilises at about 1 μg/dl.

5.6.2. Assuming a daily use of lead crystal stemware and a daily consumption of beverage equal to 5dl, the weekly lead intake caused by lead extraction from tableware would be 35 μg/week. [4]

6. Lead leaching from glass flatware

6.1. The principles set out in item 7.4. apply also to flatware, taking into account the mechanisms regulating the migration of lead from silicate surfaces.

6.2. In addition the following aspects should to be taken into consideration:

- Most tableware is classified as 'hollowware';
- Most flatware is used for decorative purpose only;
- Dry, solid food in contact with flatware is not likely to cause any significant amount of lead leaching.

7. Safety aspects

7.1. General information on safety aspects concerning lead is set out in the Guidelines on metals and alloys used as food contact materials. [12]

7.2. Maximum and guideline levels for lead in foodstuffs are laid down in Resolution AP (96) 4 of the Council of Europe [13] which cover all groups of foodstuffs that contribute significantly to the intake of lead (see Appendix 2).

7.3. Due to the recognised sources of exposure for lead and taking into account the normal use of hollowware and flatware, the exposure credit of lead for crystal articles has been established at a maximum of 10% of the total exposure.

7.4. At present the PTWI is estimated at 1,500 μg Pb/week for an adult of 60 kg body weight (216μg/day). Consequently the maximum exposure issued from glass tableware corresponds to 21 μg /day/person.

7.5. An estimation of lead intake from glass hollowware resulting from short-term exposure with several beverages under condition of use is reported in the literature [9, 10].

The worst-case calculation[10] for dietary lead intake made from glass hollowware results in 15 μg/day/person. Such an intake lies within the accepted lead exposure level set for glassware.

However the realistic estimated maximum lead exposure from glass hollowware[9] is < 5μg/day/person.

8. Test methods

8.1. Test methods for lead leaching are generally based on measures carried out with unused articles after a simple wash in water although such a testing protocol does not correspond exactly to the normal leaching pattern observed during the real use of tableware, as specified above.

8.2. On the other hand, if a testing protocol has to be selected, the benefit of choosing methods similar to other ones already established and internationally agreed is evident in the perspective of aiming at the maximum uniformity of technical rules.

8.3. The most recent test methods for the determination of lead release from glass tableware are those issued by CEN [14] and ISO. [15, 16] Whilst the test procedures in these test methods are almost identical (4% Hac, 24h, 22° +/- 2°C), the sampling and the evaluation of the results are different.

8.4. The EN method, that covers glass hollowware and flatware, does not define the acceptable limit values but specifies that in the case where one article exceeds the prescribed limit by more than 50%, the test is nevertheless carried out if 3 more articles do not exceed that limit as a mean and none of those articles exceeds the limit by more than 50%.

8.5. The ISO methods and permissible limits for hollowware and flatware are described in 2 different documents.

8.5.1. Hollowware - ISO 7086

8.5.1.1. Compared to the test method EN 1388-2, the ISO 7086 approach is more conventional. The test is conducted on 4 items and each article must result below the limit. The resultant acceptance criterion of ISO is more stringent than that foreseen by EN 1388-2.

8.5.1.2. National standards set in Partial Agreement member states, that generally prescribe test methods similar to ISO 7086-1 and EN 1388-2, establish limit values for hollowware that are less restrictive than ISO 7086-2 limit values.

8.5.2. Flatware - ISO 6486

8.5.2.1. The acceptance criteria of ISO 6486-2 requires that the mean of 4 samples be lower than the limit value.

9. Conclusions and recommendations

9.1. Studies on lead leaching from lead glass tableware show that lead intake, resulting from lead migration, does not cause risks for consumers.

9.2. Considering that the:

- test method specified in EN 1388-2 is equal to the one specified in ISO 7086 and in ISO 6486;
- acceptance criteria of ISO 7086 and ISO 6486 are more restrictive than the one of EN 1388-2;
- limit values of ISO 7086-2 and ISO 6486-2 have been recently revised;

9.3. The following recommendations are made:

9.3.1. Glass hollowware

9.3.1.1. It is recommended to apply the limit values and acceptance criteria specified in ISO 7086-2.

9.3.1.2. Summary for hollowware

Size/Type	No of samples	Permissible Limit Criterion	Limit Value
Small Hollowware	4	All samples ≤ Limit Value	1.5 mg/Liter
Large Hollowware	4	All samples ≤ Limit Value	0.75 mg/Liter
Very Large Hollowware	4	All samples ≤ Limit Value	0.5 mg/Liter

9.3.2. Glass Flatware

9.3.2.1. It is recommended to apply the limit value and acceptance criterion specified in ISO 6486-2 for flatware.

9.3.2.2. Summary for Flatware:

Size/Type	No of samples	Permissible Limit Criterion	Limit Value
Flatware	4	Mean ≤ Limit Value	0.8 mg/dm^2

9.3.3. It is recommended that before using crystal tableware, the following steps should be observed:

- Fill with a room temperature solution of 50% vinegar or citric acid (i.e. lemon juice) and 50% water;
- Let stand for 24 hours;
- Empty and rinse with warm water;
- Hand wash, using mild detergent and warm water before using to serve food and beverages.

APPENDIX 1

PARAMETERS INFLUENCING LEAD LEACHING

1. The extent of migration depends on various parameters: the type of extractant (mainly characterised by its pH and alcoholic degree), the contact time the glass composition (i.e. the variety of substances being part of the glass matrix and not only the lead oxide content), the contact temperature, the ratio between the contact surface and the volume of extracting liquid, the physical-chemical condition of the surface in contact with the liquid.

2. Extractant

2.1. The 4% Hac solution is an effective simulant for common beverages, since its extraction ability is, in general, higher than alcoholic and non-alcoholic common beverages, and its extracting pattern is similar to the real beverages. [2,3,4]

2.2. Lead leaching increases when the pH of beverage decreases, it is very low for water.

3. Contact time

3.1. It was found [3,5] that the amount of lead extracted in the first minutes of contact is a high percentage of the lead leached out after 24hrs irrespective of the type of extractant.

3.2. During the first 2 hours of contact, lead release (LR) is proportional to the square root of contact time according to the following equation:

$$LR = A + B^* \sqrt{t}$$

3.3. Where A mainly depends on the quality of contact surface and B on the chemical composition of the glass and on the extracting liquid. [3, 11]

4. Lead content in the glass

4.1. As reported earlier, some lead glasses used for tableware have a lead oxide content equal to about 6%, lead crystal and full lead crystal tableware have a lead oxide content equal to 24-25% and 30-32% respectively.

4.2. There is no strict correlation between lead oxide content in the glass and the corresponding lead release. It has been proved that lead leaching is not exclusively related to the lead content in the glass, but it is mainly connected to the ratio between network formers and modifiers of the glass matrix.

4.3. It has been proved, as well, that there is a linear relation between Pb leaching after the first contact and the hydrolytic resistance. [2]

5. Contact temperature

5.1. The lead release increases when contact temperature increases.

5.2. Some tableware is commonly used at room temperature, it is reasonable to perform leaching tests at temperatures within the range: 20 - 25°. Higher test temperatures are not recommended since they would imply the release of noxious Hac vapours.

6. Surface Area/Volume ratio

6.1. The contact surface area per unit volume of liquid varies appreciably according to the shape of the tableware; consequently, when other test conditions remain unchanged, lead release is higher for tableware having higher SA/V values.

6.2. Lead release is defined by measuring the lead concentration in the extracting liquid (i.e. mg/l), since, normally, the contact surface cannot be measured easily. Under the same test conditions (temperature, time, glass, liquid, etc.), the lead released per unit surface is independent from the shape of products.

6.3. When glass compositions of articles having different shapes are to be compared, SA/V ratios of different patterns must be calculated using a proper unit of measure (i.e. mg/dm^2). The different lead release will represent the leaching attitude of the surface.

7. Surface layer

7.1. The characteristics of the tableware contact surface depends on the bulk glass composition and, also, on their manufacturing process, storage conditions and pattern of use. (1)

7.2. A typical process that modifies the surface layer is acid polishing, aiming to restore the gloss of opaque surfaces resulting from decorative grinding and cutting operations. This process, extracting the lead available on the surface, reduces the extent of lead leaching during the following contacts.

7.3. During shipping and storage, goods are in contact with water vapours that, acting on silicon-oxygen bonds, facilitate the surface corrosion and, consequently, the lead release during the first contact.

7.4. In order to assess the risk of exposure to lead leached out from tableware, it is of basic importance to know their actual pattern of use and leaching behaviour.

APPENDIX 2

RESOLUTION AP (96) 4
ON
MAXIMUM AND GUIDELINE LEVELS AND ON SOURCE-DIRECTED MEASURES AIMED AT REDUCING THE CONTAMINATION OF FOOD BY LEAD, CADMIUM AND MERCURY

Excerpt

Maximum and guideline levels for lead

Maximum and guideline levels for lead in foodstuffs in mg/kg wet weight are laid down to cover all groups of foodstuffs that contribute significantly to the intake of lead. They are laid down using a horizontal approach and resulting in levels compatible with international toxicological assessment as expressed by a provisional tolerable weekly intake (PTWI) for each contaminant, taking into consideration relevant intake and exposure data.

Maximum and guideline levels for lead in foodstuffs

Food	Mx. level (guideline level) mg/kg
Milk and infant formulae (as consumed)	0.02
Meat and meat products, poultry (except game), except liver and kidneys	0.1
Liver and kidneys	0.5
Fish and fish products (except shellfish)	(1.0)
Molluscan bivalves and crustaceans	1.0
Fats and oils	0.1
Soft drinks and alcoholic beverages, except juices, nectars and wine	0.02
Juices of vegetables fruits and berries and nectars	0.1
Wines and fortified wines (bottled after 1993)	0.25
Fruits and berries	0.1

Food	Mx. level (guideline level) mg/kg
Vegetables, except brassica and leafy vegetables and potatoes	0.1
Brassica and leafy vegetables , except kale (*Brassica oleracea var. sabellica*)	0.1
Potatoes	0.15
Cereals, vegetables and pulses and derived products, except bran	0.1

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(18) DIN 51031: Determination of release of lead and cadmium from silicate surfaced articles intended for use in contact with foodstuffs