Draft National Standards of Food Contact Plastic Resin and Finished Articles

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1 Background
2 Revise process
3 Content & reference
4 Key feedbacks
Background of the Projects

1. Task source
   parts of 2014/2015 National Food Safety Standards clean-up projects, administrated by NHFPC.

2. Project title
   National food safety standards: Food-contact Plastic resin/finished articles

3. Responsible unit
   Food and Drug Enforcement Agency, Shanghai FDA, CFSA
Resolve the missing standards for newly approved resins (107 approved resins).

Resolve inconsistencies in the existing FCM standards related to food simulants, test conditions, limits conditions, etc.).

Clarify the responsibilities along the supply chain, and demand the traceability of toxic substances.

Solve the inadequacy of the necessary analytical method for most of the limited substances.
Revise process

- Review current standard
  - 11 Articles
  - 9 Resins
  - 107 Plastic list

- Investigate and survey manufacturing enterprise
  - convertors
  - food producers
  - food sales

Conferences
- 4 coordinating meetings
- 1 seminar
- 22 consultations

- Study foreign laws and regulations
  - EU No 10/2011
  - FDA 21crf 177

- Online public hearing
  - 81 about resin
  - 30 about article
Content and reference

Food contact plastic resin
Content and reference

1. Preface
2. Scope
3. Terms
4. General requirements
5. Technical requirements
6. Migration test requirements
7. Special requirements of use
8. Labeling and traceability (Declaration of Compliance)

www.foodcontactscience.org
Merged standards for resin

1. GB 9691-1988  Health standard for Polyethylene (PE) resin used as food packaging materials
2. GB 9692-1988  Health Standards on Polystyrene (PS) resin used as food packaging materials
3. GB 9693-1988  Health standard for Polypropylene (PP) resin used as food packaging materials
4. GB 16331-1996  Health standard for Nylon 6 (PA6 / PA66) resins for food packaging materials
5. GB 4803-1994  Health standard for PVC resin used as food container and packaging materials
6. GB 15204-1994  Health standard for Vinylidene chloride-vinyl chloride copolymer (PVdC) resins for food containers and packaging materials
7. GB 13115-1991  Health standard for Unsaturated polyester (UP) resin and glass fiber reinforced plastics used as food containers and packaging materials
8. GB 13114-1991  Health standard for Polyethylene terephthalate (PET) resin used as food containers and packaging materials
9. GB 13116-1991  Health standard for Polycarbonate (PC) resin used as food containers and packaging materials

integrated into one standard

GB XXXXX  Plastic resins for Food Contact
### Scope of GB XXXX Plastic resins for Food Contact

This standard applies to the plastic resins and mixture of resins intended to come into contact with food, including the thermoplastic elastomer resin without vulcanization and its blend.

1. **GB 9691-1988** Health standard for Polyethylene (PE) resin used as food packaging materials
2. **GB 9692-1988** Health Standards on Polystyrene (PS) resin used as food packaging materials
3. **GB 9693-1988** Health standard for Polypropylene (PP) resin used as food packaging materials
4. **GB 16331-1996** Health standard for Nylon 6 (PA6 / PA66) resins for food packaging materials
5. **GB 4803-1994** Health standard for PVC resin used as food container and packaging materials
6. **GB 13115-1991** Health standard for Vinylidene chloride-vinyl chloride copolymer (PVdC) resins for food containers and packaging materials
7. **GB 13114-1991** Health standard for Unsaturated polyester (UP) resin and glass fiber reinforced plastics used as food containers and packaging materials
8. **GB 13116-1991** Health standard for Polyethylene terephthalate (PET) resin used as food containers and packaging materials
9. **GB 13117-1991** Health standard for Polycarbonate (PC) resin used as food containers and packaging materials
This standard applies to the plastic resins and articles intended to come into contact with food, including the thermoplastic elastomer resin without vulcanization and its blend.

Solved problems

1. Applicable to the resin type covered by current resin standards.
2. Solve the problem of standardless status for the 107 kinds of resins in the bulletin.
3. Suitable for the new resin category to be approved in the future.

Advantages: standardize the safety requirements, and no need to develop one standard for each resin.
Resin (polymer)

A long chain molecule formed by the addition, condensation and fermentation of starting materials. It also includes the chemically modified natural macro molecule.

Blends of resins

A uniformed and continuous solid material formed by mixing, chemically or physically, two or more polymers with different chemical structure or physical phase. It is also called polymer alloy.
General requirements

Plastic food contact materials shall comply with the requirements stated in “National food safety standards-general safety requirements on Food contact materials and products.”

The food contact plastic materials and articles: shall not endanger human health;

shall not have any technical effects on foodstuffs;

shall not lead to unacceptable changes in food components and organoleptic characteristics.
Specifications of monomer and additives

• The specifications and purity of the monomers and other starting materials should ensure the safety of finished plastic articles and should not endanger human health under normal and expected use conditions;

• The permitted list of the food contact plastic resin should comply to the requirements stated in annex A and the related announcement.
Technical requirements

- The SML and residues of the monomers and other starting materials should comply with the requirements stated in annex A and the related announcement.

- Additives used in food contact plastic articles should comply with the requirements in GB 9685.
Technical requirements

Comparison of old and new standards

- PE, PP, PS, PET, PC:
  - Keep all existing physical and chemical indicators (see Appendix A notes)

- PA6:
  - Caprolactam elution 150mg/L → 15mg/kg;

- PVDC:
  - Vinylidene chloride residue 10mg/kg → 5mg/kg, SML ND;
  - VCM residue, 2mg/kg → 1mg/kg, SML ND

- PVC
  - Modified 1,2-Dichloroethane from 150mg/kg to 5mg/kg;
  - Add 1,2-Dichloroethane SML ND (DL=0.01mg/kg)
  - Modification of vinyl chloride residues from 5mg/kg to 2mg/kg to 1mg/kg; SML, ND (DL=0.01mg/kg);
  - Remove 1,2-Dichloroethane residues
Other requirements

Migration tests
Migration tests must be conducted in accordance with GB31604.1 Guideline to migration test methods of food contact materials and the requirements in GB 5009.156. Unless otherwise specified.

Labeling and traceability
Label must contain information regarding to the resin types and the main polymer materials of polymer blends. All suppliers in the supply chain must ensure the communication of safety information and the traceability of the harmful substances and restricted substances.

Declaration of Compliance
Appendix A list of permitted plastic resins

Source

- 102 kinds of resin list
- 90 from the announcement
- 12 from previous standard (see Table 2)

Changes

- Modify the name of the 51 polymers;
- Add SML of 59 chemicals or groups;
- Add QM of 19 chemicals or groups.

The table 2 and table 3 of standard explanatory document show the major changes of the polymer name and its reference.
Appendix A list of permitted plastic resins

SML/SML(T) reference

SML of 59 kinds of monomer modify the GB, formaldehyde, melamine, caprolactam, free phenol, Vinyl chloride, acrylonitrile according to EU/CODEX

The other 57 according to EU

QM reference

QM of 21 kinds of chemicals or groups;
6 substances were modified: vinyl chloride acrylonitrile, caprolactam, styrene, ethyl benzene, 1,1-vinylidene chloride;
modify styrene, ethyl benzene, phenol according to GB, others according to EU

The reference for the formulation of the specific migration limits and the amount of residues
Major changes in the amount of migration and residual of current national standard

<table>
<thead>
<tr>
<th>Monomer and others</th>
<th>SML (mg/kg)</th>
<th>QM (mg/kg)</th>
<th>Modified to (mg/kg)</th>
<th>reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>acrylonitrile</td>
<td>/</td>
<td>/</td>
<td>GB 17626 ABS article 11</td>
<td>SML 0.01; QM 0.1</td>
</tr>
<tr>
<td></td>
<td>/</td>
<td>/</td>
<td>GB 17627 AS article 50</td>
<td></td>
</tr>
<tr>
<td>Vinyl chloride</td>
<td>/</td>
<td>/</td>
<td>GB 15204 PVDC resin 2</td>
<td>SML 0.01; QM 0.1</td>
</tr>
<tr>
<td></td>
<td>/</td>
<td>/</td>
<td>GB 4803 PVC resin 5</td>
<td></td>
</tr>
<tr>
<td></td>
<td>/</td>
<td>/</td>
<td>GB 9681 PVC resin 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>/</td>
<td>/</td>
<td>GB 14944 PVC resin 1</td>
<td></td>
</tr>
<tr>
<td>caprolactam</td>
<td>GB 16332 PA article 15mg/L</td>
<td>GB 16331 PA6 resin 150mg/L</td>
<td>SML 15</td>
<td>EU</td>
</tr>
<tr>
<td>formaldehyde</td>
<td>/</td>
<td>2.5mg/dm2</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>melamine</td>
<td>GB 9690 MF article 0.2mg/dm2</td>
<td>/</td>
<td>/</td>
<td>2.5 (1.0)</td>
</tr>
<tr>
<td>Free phenol</td>
<td>GB 14942 PC article 0.05mg/L</td>
<td>/</td>
<td>/</td>
<td>/ retain</td>
</tr>
<tr>
<td></td>
<td>GB 13116 PC resin 0.05mg/L</td>
<td>/</td>
<td>/</td>
<td>/ retain</td>
</tr>
<tr>
<td></td>
<td>GB 16332 PA article 0.05mg/L</td>
<td>/</td>
<td>/</td>
<td>/ retain</td>
</tr>
<tr>
<td>styrene</td>
<td>/</td>
<td>/</td>
<td>GB 13115 UP resin Resin 0.20%, composite 0.01%</td>
<td>retain</td>
</tr>
<tr>
<td></td>
<td>/</td>
<td>/</td>
<td>GB 9692 PS resin 0.50%</td>
<td></td>
</tr>
<tr>
<td>Ethyl benzene</td>
<td>GB 9692 PS resin 0.30%</td>
<td>/</td>
<td>/</td>
<td>/ retain</td>
</tr>
<tr>
<td>1, 1-2 vinyl chloride</td>
<td>GB 4803 PVC resin 150mg/kg</td>
<td>SML, ND(DL=0.05)</td>
<td>EU</td>
<td></td>
</tr>
<tr>
<td></td>
<td>/</td>
<td>/</td>
<td>GB 15204 PVDC resin 10mg/kg</td>
<td></td>
</tr>
</tbody>
</table>

delete the 1, 2 - dichloroethane residue
### 8 kinds of non-detectable and limit of detection

<table>
<thead>
<tr>
<th>No.</th>
<th>name</th>
<th>107 resin SML(mk/kg)</th>
<th>Polymer code</th>
<th>acronym</th>
<th>reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Vinyl chloride</td>
<td>ND (DL=0.01)</td>
<td>29,30</td>
<td>PVC, PVDC</td>
<td>EU 10/2011, CODEX</td>
</tr>
<tr>
<td>2</td>
<td>Copolymer of Bisphenol A, and chloromethyl oxirane</td>
<td>ND (DL=0.01)</td>
<td>102</td>
<td>Bisphenol A Epoxy resin</td>
<td>EU 10/2011</td>
</tr>
<tr>
<td>3</td>
<td>1, 3 - butadiene</td>
<td>ND (DL=0.02)</td>
<td>10,11,12,13,15</td>
<td>PS, AS, ABS, PAN</td>
<td>EU 10/2011</td>
</tr>
<tr>
<td>4</td>
<td>1,3- benzenediamine</td>
<td>ND (DL=0.02)</td>
<td>96,97,99</td>
<td>PEI</td>
<td>EU 10/2011</td>
</tr>
<tr>
<td>5</td>
<td>Acrylonitrile</td>
<td>ND (DL=0.02)</td>
<td>12, 13, 14, 15, 31</td>
<td>ABS, AS, PAN, PVDC</td>
<td>EU 10/2011, CODEX</td>
</tr>
<tr>
<td>6</td>
<td>Methyl acrylamide</td>
<td>ND (DL=0.02)</td>
<td>25</td>
<td>PMMA</td>
<td>EU 10/2011</td>
</tr>
<tr>
<td>7</td>
<td>Isoprene</td>
<td>ND (DL=0.02)</td>
<td>11</td>
<td>PS</td>
<td>EU 10/2011</td>
</tr>
<tr>
<td>8</td>
<td>1, 1-vinyl chloride</td>
<td>ND (DL=0.05)</td>
<td>30, 31.32</td>
<td>PVDC</td>
<td>EU 10/2011</td>
</tr>
</tbody>
</table>

Limit of detection is noted in the 107 kinds of resin announcement, and aligned to 0.01mg/kg
Major feedback

About the requirement:
Remove some physiochemical parameters, including total migration, potassium permanganate consumption, heavy metal (as lead), color migration

Advice about whether to remove the remark for the use limitations:
- Cancel the defined max usage temperature, can be adjusted based on the migration test results;
- Cancel the limit of food type, can be adjusted according to migration result;
- Relevant supporting information needed
Food contact plastic materials and articles
### Merged standards for article

<table>
<thead>
<tr>
<th>Standard</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>GB 9681-1988</td>
<td>Hygienic standard for polyvinyl chloride products used as food containers and tablewares</td>
</tr>
<tr>
<td>GB 9687-1988</td>
<td>Hygienic standard for polyethylene products used as food containers and tablewares</td>
</tr>
<tr>
<td>GB 9688-1988</td>
<td>Hygienic standard for polypropylene products used as food containers and tablewares</td>
</tr>
<tr>
<td>GB 9689-1988</td>
<td>Hygienic standard for polystyrene products used as food containers and tablewares</td>
</tr>
<tr>
<td>GB 9690-2009</td>
<td>Hygienic standard for melamine-formaldehyde products used as food containers and packaging materials</td>
</tr>
<tr>
<td>GB 13113-1991</td>
<td>Hygienic standard for polyethylene terephthalate products used as food containers and packaging materials</td>
</tr>
<tr>
<td>GB 14942-1994</td>
<td>Hygienic standard for polycarbonate products used as food containers and packaging materials</td>
</tr>
<tr>
<td>GB 14944-1994</td>
<td>Hygienic standard of bottle sheet and granular materials of polyvinyl chloride for food packaging</td>
</tr>
<tr>
<td>GB 16332-1996</td>
<td>Hygienic standard of products of nylon for food packaging material</td>
</tr>
<tr>
<td>GB 17326-1988</td>
<td>Hygienic standard for rubber-modified acrylonitrile-butadiene-styrene products used as food containers and packaging materials</td>
</tr>
<tr>
<td>GB 17327-1988</td>
<td>Hygienic standard for acrylonitrile-styrene products used as food containers and packaging materials</td>
</tr>
<tr>
<td>GB 13115-1991</td>
<td>Hygienic standard of unsaturated polyester resin and glass fibre reinforced plastics used as food containers and packaging materials</td>
</tr>
</tbody>
</table>

**GB XXXX-201X Food contact plastic materials and products**
This standard applies to food contact with plastic materials and products (including non vulcanized thermoplastic elastomer materials and products).

**Solve the problems**

1. Applicable to the resin type covered by current resin standards.
2. Solve the problem of non standard for the 107 kinds of resins in the bulletin.
3. Suitable for the new resin category approved in the future.

Advantages: standardize the safety requirements, and no need to develop one standard for each resin
**Plastic Material**

- A polymeric material made from one of more resins (polymer), with or without additives, processed under certain temperature and pressure, holding a defined shape, remaining between resin and article. Including plastic granules (slice), master batch, sheet.

**Plastic Article**

- Articles made from plastic resin or article, with or without additives, holding a defined shape.

**Master Batch**

- A type of resin with overloaded additives (colorant, filler, fibre, stabilizer). Used together with other resins to form the final article.
# Physicochemical Requirements

## Tabel 2 Physicochemical Requirements

<table>
<thead>
<tr>
<th>Test item</th>
<th>limit</th>
<th>Test method</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>OM</strong>&lt;sup&gt;a&lt;/sup&gt; Infant use/(mg/kg)</td>
<td>≤10mg/dm&lt;sup&gt;2&lt;/sup&gt;</td>
<td>GB 31604.8</td>
</tr>
<tr>
<td>Others /(mg/dm2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Potassium permanganate consumption</strong>/(mg/kg)</td>
<td>≤12</td>
<td>GB 31604.2</td>
</tr>
<tr>
<td>Distilled water (60 °C, 2 h)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Heavy metals (as lead)</strong>/(mg/kg)</td>
<td>≤1.2</td>
<td>GB 31604.9</td>
</tr>
<tr>
<td>4% (v/v) acetic acid (60 °C, 2 h)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Color migration</strong> b</td>
<td>negative</td>
<td>GB 31604.7</td>
</tr>
</tbody>
</table>

a. contact in infant food should be in 60 mg/kg or less.
b. is limited to add colorant products.

Current GB requirements of plastic articles
### 表 1 食品类别与食品模拟物

<table>
<thead>
<tr>
<th>食品类别</th>
<th>食品模拟物</th>
</tr>
</thead>
<tbody>
<tr>
<td>水性食品，乙醇含量≤10%（体积分数）</td>
<td>10%（体积分数）乙醇或水</td>
</tr>
<tr>
<td>非酸性食品（pH≥5）</td>
<td>4%（体积分数）乙酸</td>
</tr>
<tr>
<td>酸性食品（pH＜5）</td>
<td></td>
</tr>
<tr>
<td>含酒精饮料，乙醇含量＞10%（体积分数）</td>
<td></td>
</tr>
<tr>
<td>乙醇含量≤20%（体积分数）b</td>
<td></td>
</tr>
<tr>
<td>20%（体积分数）＜乙醇含量≤50%（体积分数）</td>
<td>50%（体积分数）乙醇</td>
</tr>
<tr>
<td>乙醇含量＞50%（体积分数）</td>
<td>实际浓度或95%（体积分数）乙醇</td>
</tr>
</tbody>
</table>

| 油脂及表面含油脂食品 | 植物油d |

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a 对于乙醇含量≤10%（体积分数）的食品和不含乙醇的非酸性食品应首选10%（体积分数）乙醇，如食品接触材料及制品与乙醇发生酯交换反应或其他理化改变时，应选择水作为模拟物，水的质量应符合相关标准规定。
b 也适用于富含有机成分且使食品的脂溶性增加的食品。
c 也适用于水包油乳化食品（如部分乳及乳制品）。
d 植物油为精制玉米油、橄榄油，其质量要求应符合 GB 5009.156 的规定。

Source: GB31604.1 Guideline to migration test methods of food contact materials
Changes

- Modify evaporation residue to total migration;
- Modify food simulant, which varies according to food in contact with;
- Modify migration test conditions, which vary according to the actual use;
- Retain the potassium permanganate consumption, the limit was converted by 6:1;
- Retain heavy metals (lead), the limit was conversed by 6:1;
- Retain color migration.
Schematic diagram of the formation of plastic article (exemplified with thermoplastic)
Questions & Answers

THANK YOU