

For a safer world

The Reform of Chinese FCM regulations and the legal compliance

Part 2

**National reference laboratory for
Food contact material(NRL-FCM-IQTC)**

钟怀宁 Zhong Huai ning
Marco_zhong@iqtc.cn , 13924163757

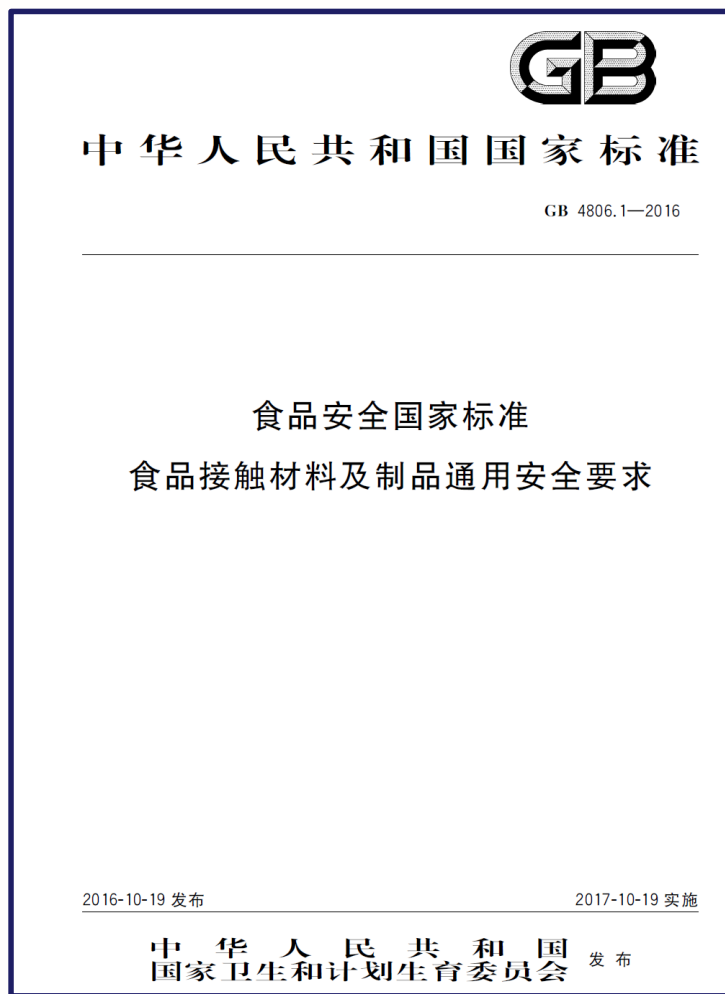


广东检验检疫技术中心

Guangdong Inspection and Quarantine Technology Center



General safety requirement for FCM GB 4806.1-2016



2016-10-19 approved

2017-10-19 come into enforce

GB 4806.1 General safety requirement

Scope

–Address the basic requirement ,limitation, rules for compliance, methods, traceability and information for products

–Apply for all kind of FCMs

Packaging、 container、 utensil and instrument, or coating, inks, adhesive, lubricant, etc , that will directly or indirectly contact with food.

- *Already contacted*
- *Intend to contact*
- *It is believed to migrate into food*

Detergent, disinfectant and public water supply facility not included

Basic requirements

Three of “shall not”

The migration of constituents in quantities to food

- *Shall not endanger the human health* *under intended/foreseeable use*
- *Shall not cause the change* *of composition and organoleptic character*
- *Shall not introduce the technical effect* *on packaged food(not applicable in special circumstances)*
e.g.: active & intelligent material



Basic requirements

Usage amounts

- Reduce the usage amounts as low as possible if the intended effect has been achieved.

Quality criteria

- The substances used shall meet the quality criteria .

GB 9685, Notification and specific standards

NIAS

- The manufactures shall control the non-intentionally added substances in FCMs

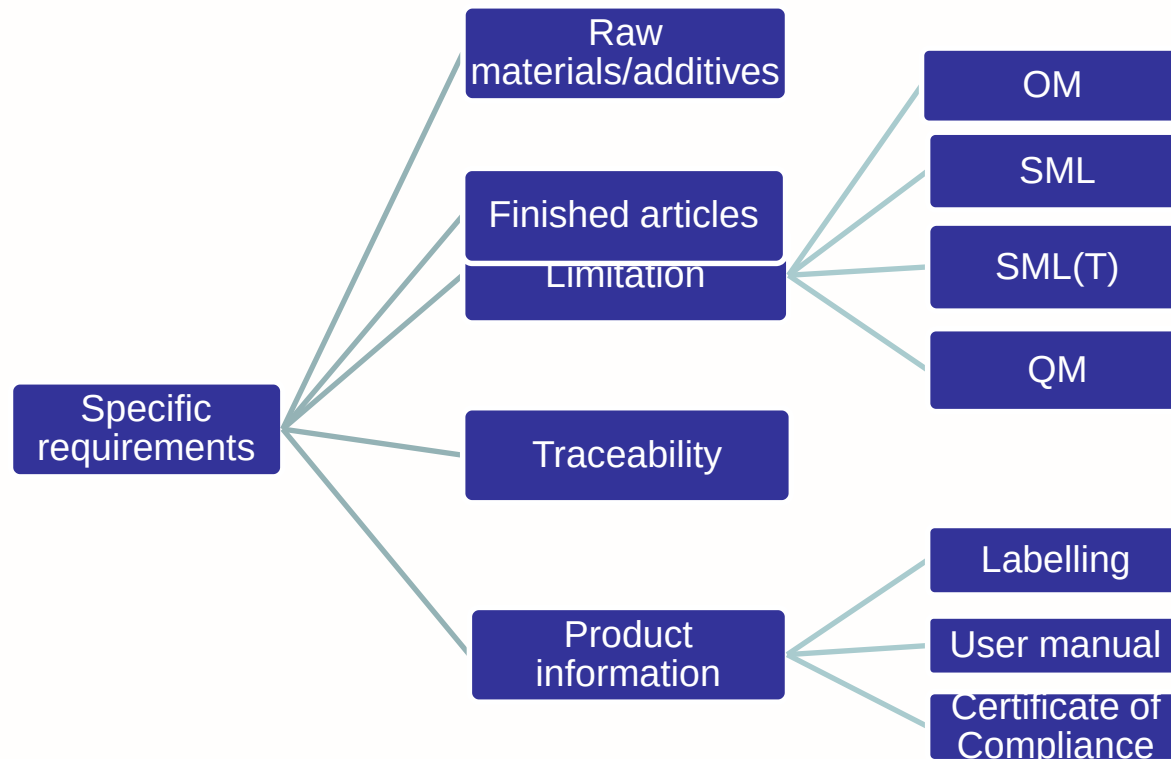
Management of non-approved substances

- For those non-approved substances that are not directly contact with food and blocked by functional barrier, the manufactures shall perform **safety assessment** and to take appropriate **control measures**, ensuring the migration shall not exceed 0.01mg/kg of food.

GMP

- The manufacturing of FCM shall comply with GB 31603-2015 , **Come into enforce on 21th, Sept.,2016**

Specific requirements



In 18th, November, 2016, 50 safety standards published by National Health and Family Planning Commission and has come into enforce in April, 2017

- Standards for materials and articles
- Standards for testing
- Standards for

How to demonstrate the compliance



FCM can be sold, only when fulfil the following requirements:



**General safety requirement
GB 4806.1-2016**

key points

Use of chemicals

- Only authorized substance/material can be used
- GB 9685, Notification

Use of Non-authorized substances

- **can be used if :**
 - *Not directly contact with food*
 - *Blocked by functional barrier*
 - *Not exceed 0.01mg/kg of food*
 - *Not Carcinogenic, mutagenic, teratogenic and Nano-material*

Compliance of GMP

- Carefully look at the relevant provisions in GB 31603
- It is acceptable to demonstrate by a way of self-claim or to obtain a certificate issued by a third-party body



key points

Labeling& identification

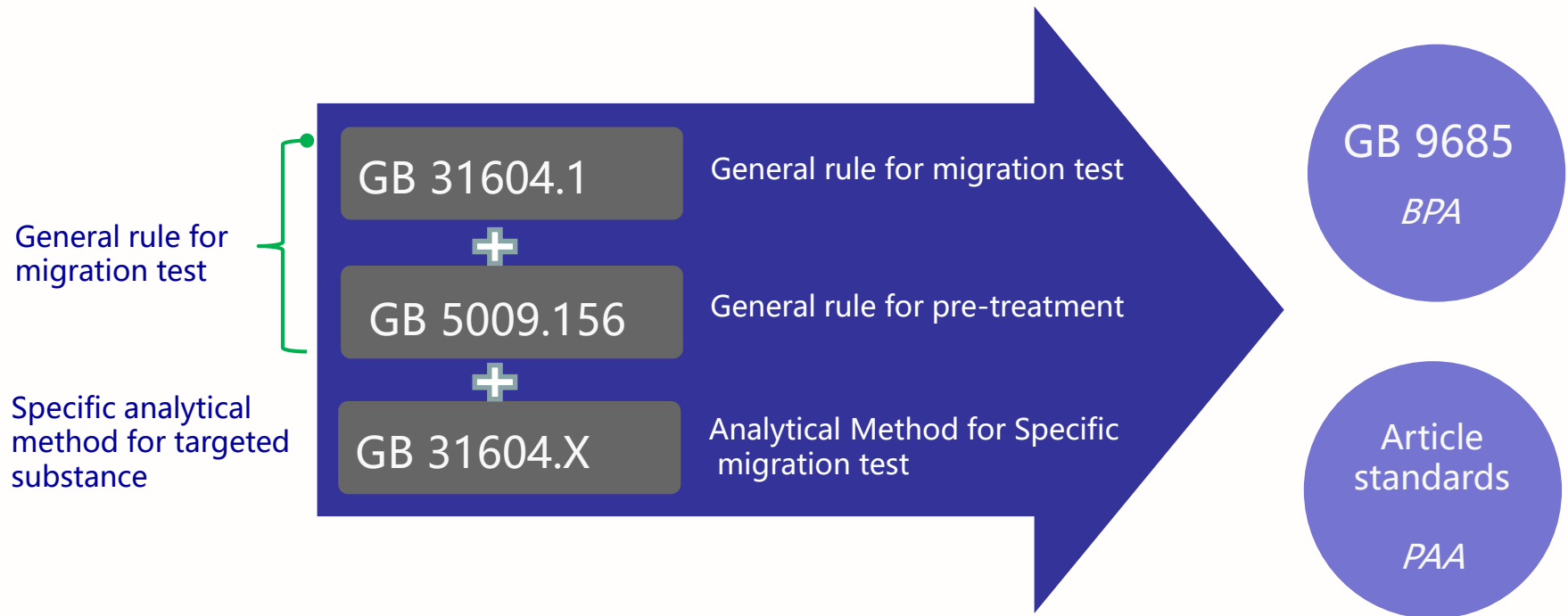
- Symbol ,or
- Wording of “for food contact “or “for food packaging” or
- No indication needed if it is clear that the article will be used for food Packaging or contact application, e.g. kitchenware



Declaration of compliance

- Corresponding regulation and standards
- List of substances with restriction, **NOT THE FULL LIST OF INGREDIENTS**
- The measures taken to demonstrate the compliance (Assessment of NIAS)
- Supporting technical documents(analytical report)

Migration test



The workflow of performing compliance



- Collect product information and DOC from upstream supplier



- Understand the intend use



- Apply appropriate regulation/standard based on information collected



- Check if the raw material and additives authorized for use based on regulation/standards



- Perform assessment of NIAS based on expert judgement, DOC and screening measures(TTC, Analytical approach)



- Perform migration test on targeted substances by using appropriate technics or analytical methods



- Compare the result obtained with the requirement of regulation, check the compliance



- Carry out GMP audit



- Prepare the declaration of compliance and supporting documents

Conclusion



- *The legal compliance shall be fulfilled in the whole supply chain*
- *Each shareholders share the common interest and have the duty to demonstrate the compliance*
- *There is a urgent need for the transfer of information from upper supplier to the end user*



For a safer world

Thank you for your attention !

保护消费者、保护您的业务和您的品牌



**National reference laboratory for
Food contact material**

钟怀宁 Marco Zhong

Marco_zhong@iqtc.cn 0086-20-87004041, 13924163757