

Compliance of Food Contact Materials in China



Name: Aaron Cheng
Title: FCM Business Manager

REACH24H



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PART 01

A Brief Introduction to FCM Regulations in China

Definition of FCM

Food contact materials & articles

GB 4806.1 General Standard

Materials and articles in contact or intended to come into contact with food or food additives.

Including:

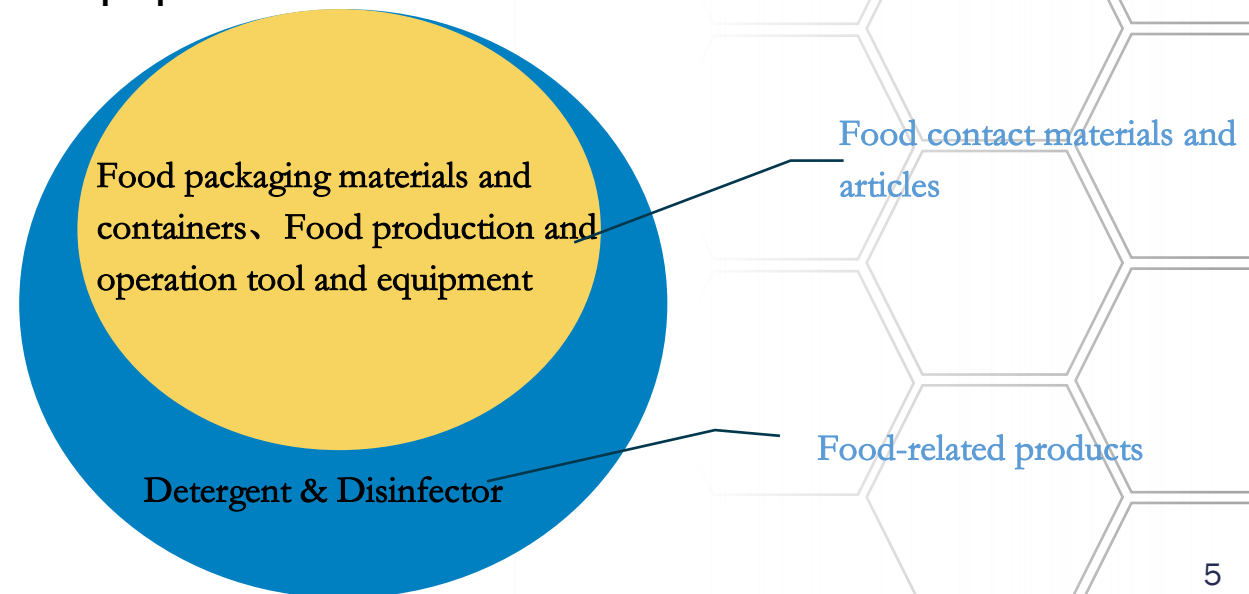
- Food packaging materials, containers, utensils and machines that directly contact with food during food production, processing, packaging, transportation, storage and selling;
- Printing ink, adhesive, grease that may directly or indirectly contact food;

***Detergents, disinfectors and public water delivery facilities are excluded.**

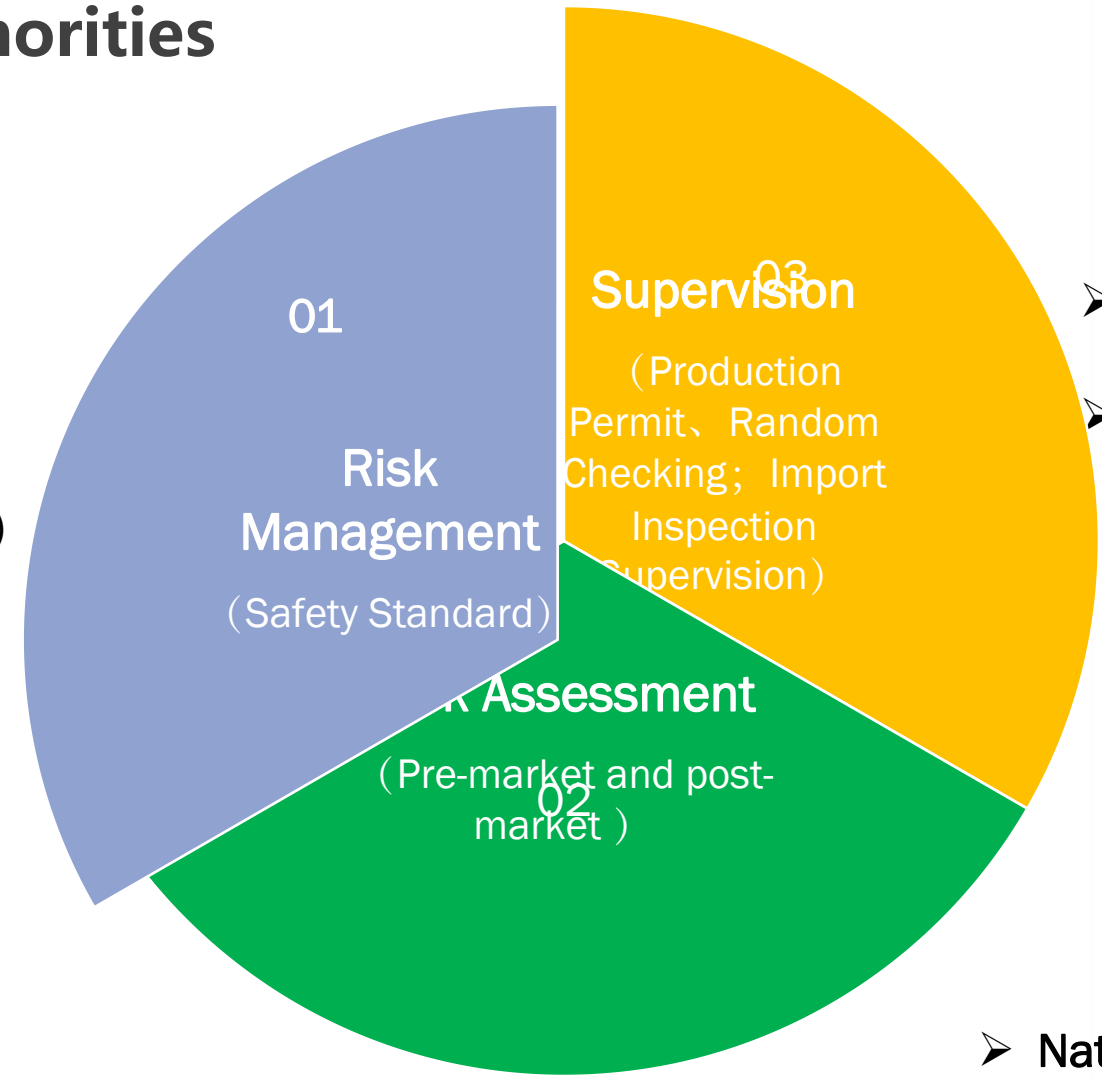
Food-related products

Food Safety Law

1. Food packaging materials and containers
2. Detergent
3. Disinfectant
4. Food production and operation tool and equipment



Competent Authorities

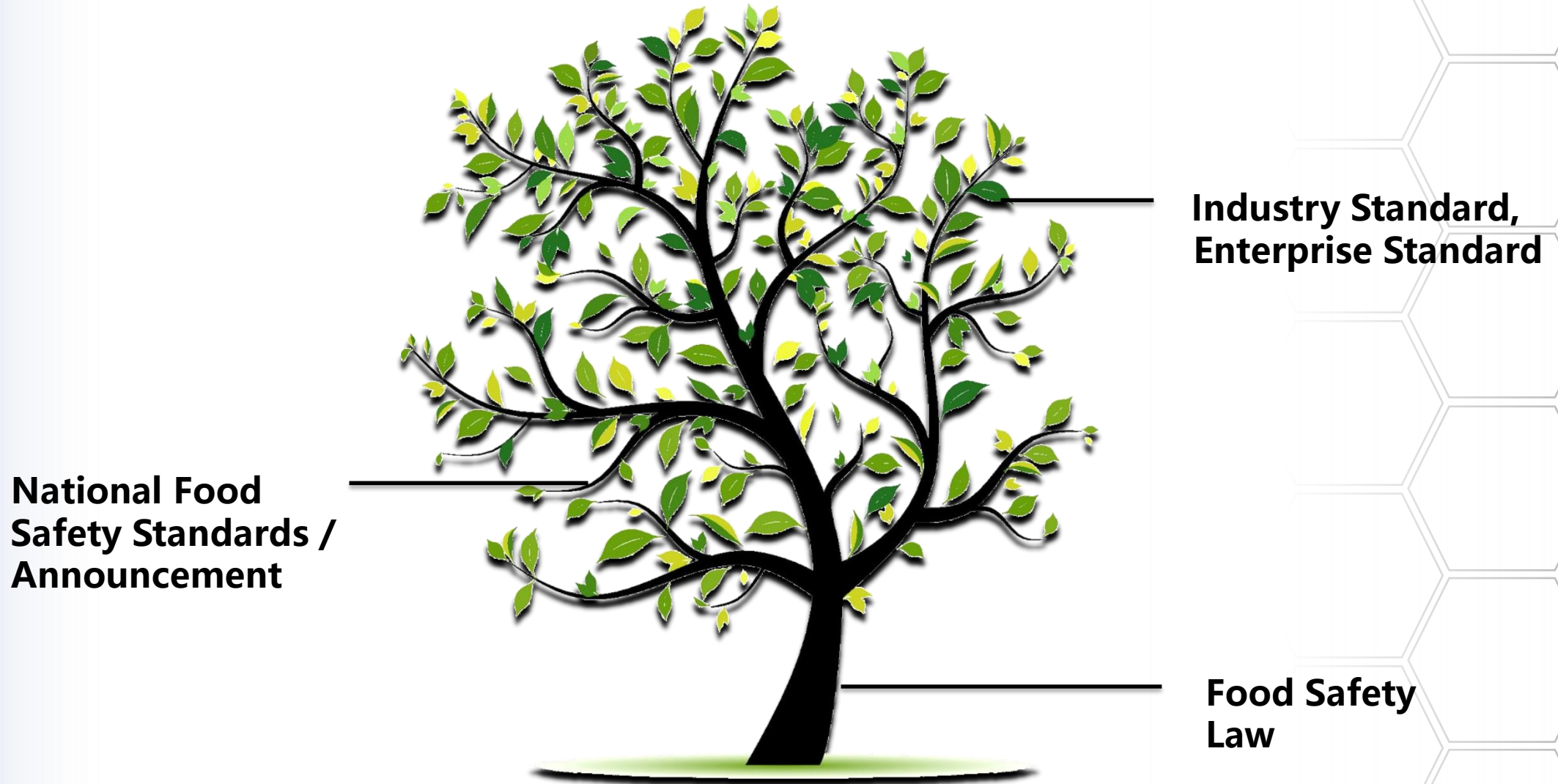


- **National Health Commission(NHC)**
National Center for Food Safety Risk Assessment (CFSA)

- **State Administration for Market Regulation (SAMR)**
- **General Administration of Customs. P.R. China(GACC)**

- **National Health Commission (NHC)**
National Center for Food Safety Risk Assessment (CFSA)

Regulatory Framework



Food Safety Law

Article 2

- The range of **Food-related** product.

Article 37

- **New varieties of food-related products** shall submit the safety assessment materials relative to the product to the NHC, and those that meet the food safety requirements shall be licensed and published.

Article 41

- Food related products of higher risks, such as packaging materials that directly contact foods, are subject to **production licensing of relevant industrial products**.

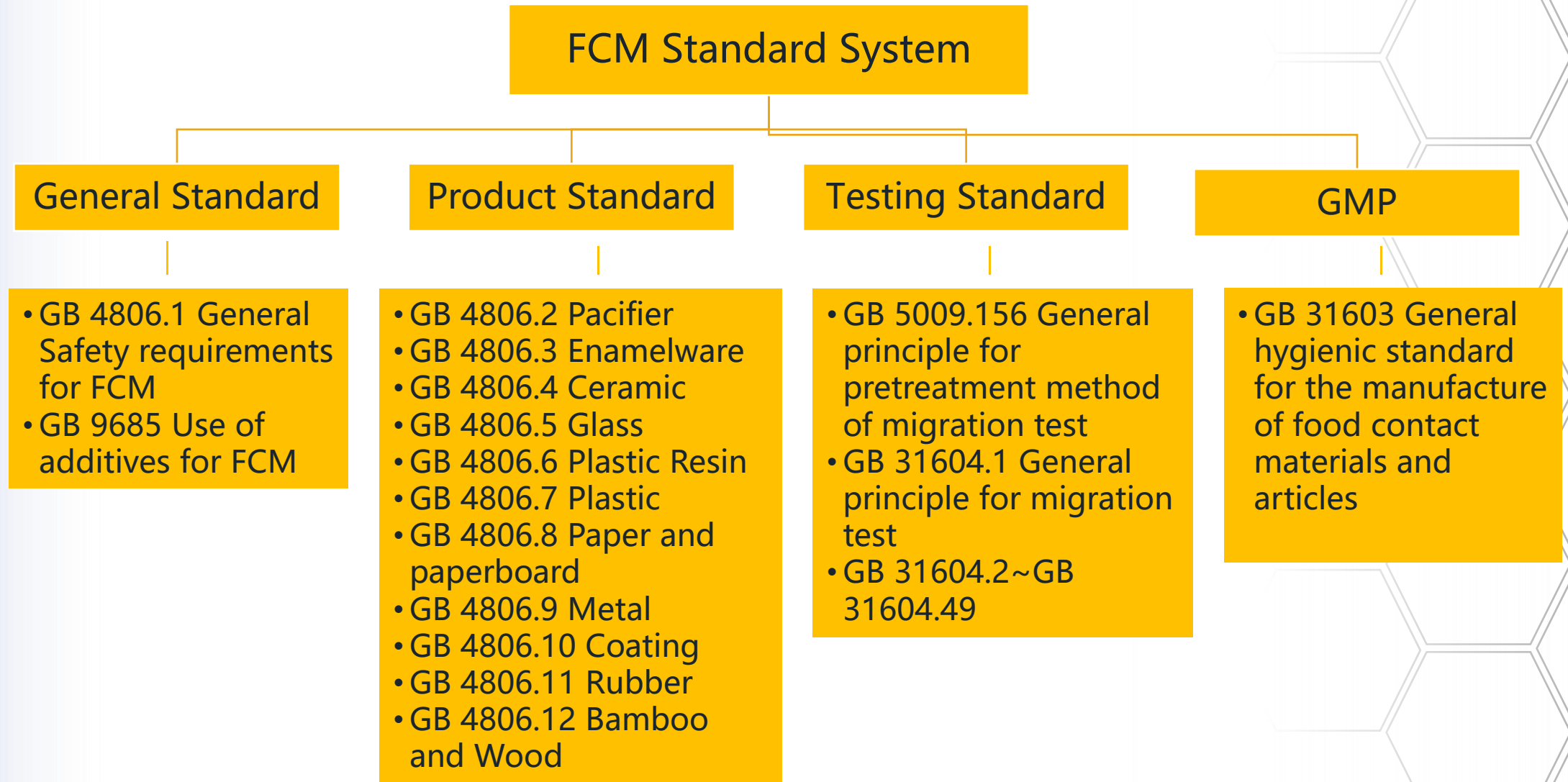
Article 52

- Producers of food-related products should conduct **inspections** in accordance with food safety standards, and can only leave the factory or sell them after the inspections are compliant.

Article 92

- **Imported food** packaging materials must comply with national food safety standards.

FCM Standard System



GB4806.1 General Safety Requirements for FCM and articles

3 BASIC REQUIREMENTS

- 3.1 The quantity of substances migrated to food **should not endanger human health under the intended use.**
- 3.2 Substances migrated into food should **not cause changes to composition, structure or color, aroma and flavor** of the food and **not cause technical effects on the food** (except for specific stipulations)
- 3.3 **The amount of substance** used in the FCM and articles **should be as lower as possible** under the premise of achieving expected effects.
- 3.4 The substance used in the FCMs and articles should meet the corresponding quality specification.
- 3.5 The manufacturers should conduct safety evaluation for **the unintentionally added substances** in the products and those generated during the production, and control over the substances to make sure that the migration level met the requirements of section 3.1 and 3.2 in the standard.

GB4806.1 General Safety Requirements for FCM and articles

3 BASIC REQUIREMENTS

3.6 For substances that are isolated from food by functional barrier or do not listed in the corresponding national food safety standards, manufactures shall conduct safety assessments and control over them to make sure that the migration level is less than 0.01 mg/kg.

Carcinogenic, teratogenic and mutagenic substances and nano-materials are not application.

3.7 The production shall meet the requirements of GB 31603.

8 PRODUCT INFORMATION

8.2&8.3 FCM and articles need **label** and **Declaration of Compliance**.

8.4 Compliance statement should contain information of regulations and standards in compliance with, restricted substance and its limitation, the evaluation information of the unintentionally added substances and the compliance of overall migration level (for products only) etc.

8.5. Words such as **“for food contact use”**, **“for food package use”** should be instructed on FCM and articles, or **mark of spoon and chopsticks** should be stamped or pasted.



图 A.1 调羹筷子标志图

Updates on FCM Standards

New Standards under development	Current standards under revision
<ul style="list-style-type: none">● Bamboo and wood products (Draft for Comments was published in 2020, officially released in July 2022)● Adhesive (First Draft for Comments was published in 2019, Second Draft for Comments was published in 2021)● Printing Ink (Draft for Comments was published in 2020)● Cellulosic material (Being drafted)● Starch-based Plastics (Draft for Comments was published in 2018, will be integrated into the revised GB 4806.7 Plastics Standard)	<ul style="list-style-type: none">● Composite materials and products (Draft for Comments was published in 2020)● Metal (Draft for Comments was published in 2020)● Paper and Paperboard (Draft for Comments was published in 2020, officially released in July 2022)● Plastics (Draft for Comments was published in 2021)● Coating (Draft for Comments was published in 2021)● Rubber (Draft for Comments was published in 2021)● Silicone Rubber (Being drafted)● General principle for migration tests (Draft for Comments was published in 2021)

PART 02

Supply Chain Compliance

Supply Chain Responsibilities of Stakeholders



Chemical
substances
manufacturer

Intermediate
materials
manufacturer

Finished
product
manufacturer

Finished
product user

Consumer



Supply Chain Responsibilities of Stakeholders

- **Chemical substances manufacturer**

- Food contact materials need to be listed in the corresponding positive list, comply with the corresponding production specifications, meet the corresponding quality specifications, and **provide the Declaration of Compliance to the downstream.**
- If the food contact materials are **not listed** in the positive list, it must be approved **by submitting the new food contact substance application.**

- **Intermediate material manufacturer**

- Responsible for the substances/ materials used/ added/ produced in the manufacturing process, confirming that they meet the requirements of corresponding regulations and comply with the corresponding production specifications; **request the Declaration of Compliance from the upstream customers and need to provide a Declaration of Compliance of the intermediate materials to their downstream customers.** Voluntary to conduct migration test.
- If the food contact materials are **not listed** in the positive list, it must be approved **by submitting the new food contact substance application.**

Supply Chain Responsibilities of Stakeholders

•Finished product manufacturer

–Responsible for the substances/ materials used/ added/ produced in the manufacturing process, confirming that they meet the requirements of corresponding regulations and comply with the corresponding production specifications; **request the Declaration of Compliance from the upstream customers** and need to **provide a Declaration of Compliance of the finished product to their downstream customers. Test the physicochemical indexes of the product and carry out required migration testing.**

–When selling products directly to the **consumers**, there is no need to provide the Declaration of Compliance, but the **label** should be provided in accordance with GB4806.1.

–If the food contact materials are **not listed** in the positive list, it must be approved by **submitting the new food contact substance application.**

•Finished product user

–**Request the Declaration of Compliance from the upstream customers** and use the product in accordance with the Declaration of Compliance passed by the upstream to ensure the final food safety.

•Consumer

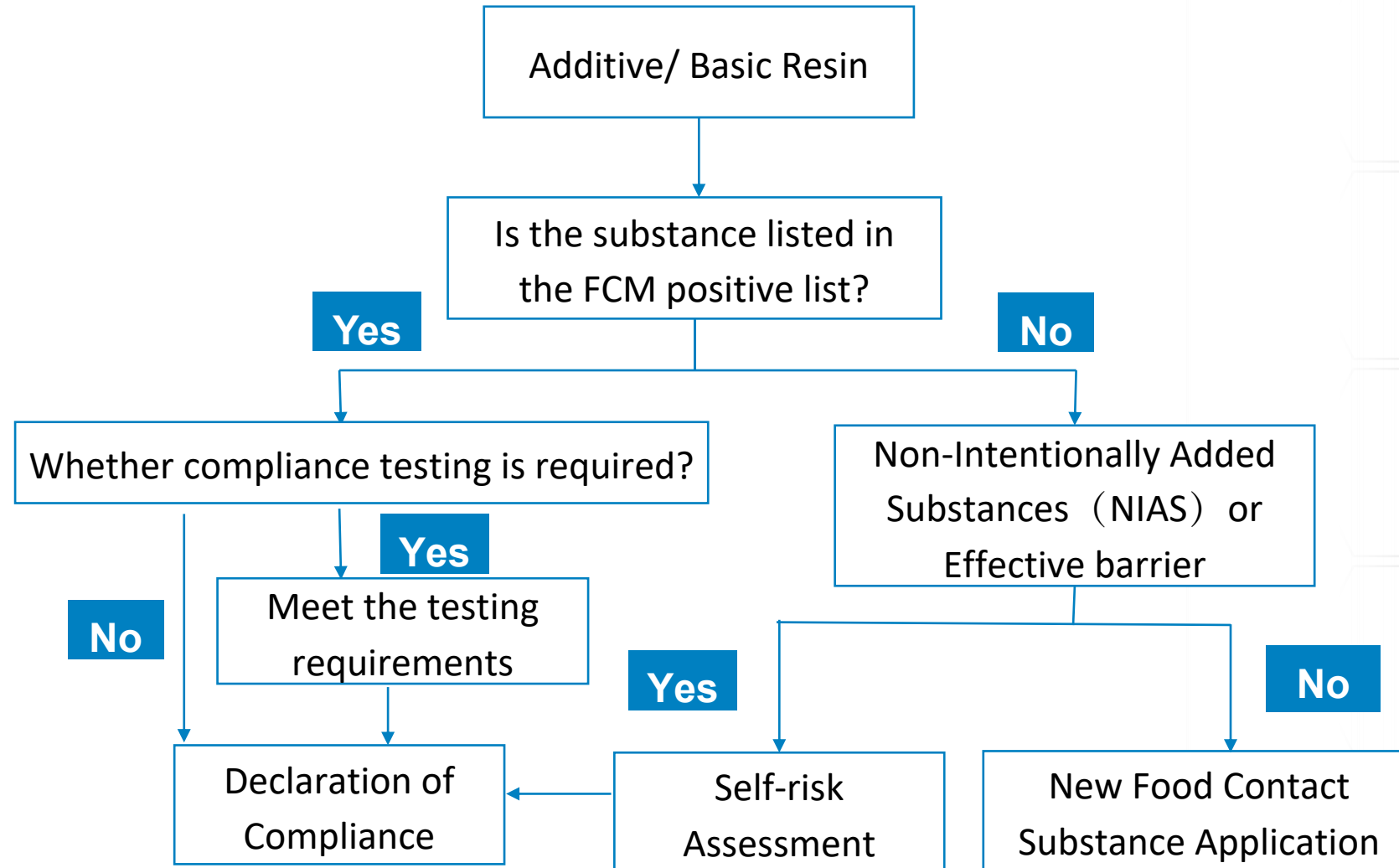
–Consumers should **abide by the labeling or instructions for use**, and use the product correctly, especially the restrictive use conditions, such as the category for food contact, the time and temperature control when contacting food.

Regulatory Reference for Food Contact Materials

Take Food Contact Plastics as an Example

	Basic requirements	Raw material requirements		Product requirements	Migration test requirements	Good Manufacturing Practice
		Additive	Basic raw materials			
Related standard	GB 4806.1	GB 9685	GB 4806.6 (resin)	GB 4806.7 (plastic materials and articles)	GB 31604.1 GB 5009.156	GB 31603
Specific requirements	<ol style="list-style-type: none"> 1. Use basic principles 2. NIAS control 3. Use of safety thresholds 4. Product information (labels, compliance requirements, etc.) 	<ol style="list-style-type: none"> 1. Additives are listed in GB 9685 table A.1 or announcement, and the scope of use includes PET, or conforms to the principle of A.13 2. Meet the limited and special use requirements 3. The colorant should meet the specifications 	<ol style="list-style-type: none"> 1. The resin is listed in Appendix A of GB 4806.6 or the announcement 2. Compliance with limited and special use requirements 3. Special label requirements 	<ol style="list-style-type: none"> 1. Physicochemical indexes such as total migration limit, potassium permanganate consumption, heavy metals, etc. 2. The monomer and starting material meet the corresponding limit regulations and special use requirements 3. Special label requirements 	<ol style="list-style-type: none"> 1. Migration test for finished product 2. Condition selection, pre-treatment, etc. meet the requirements of the two basic migration tests 3. The specific indicators follow the national standard testing method or other technically verified methods 	Plants, facilities, personnel, sanitation management, etc.

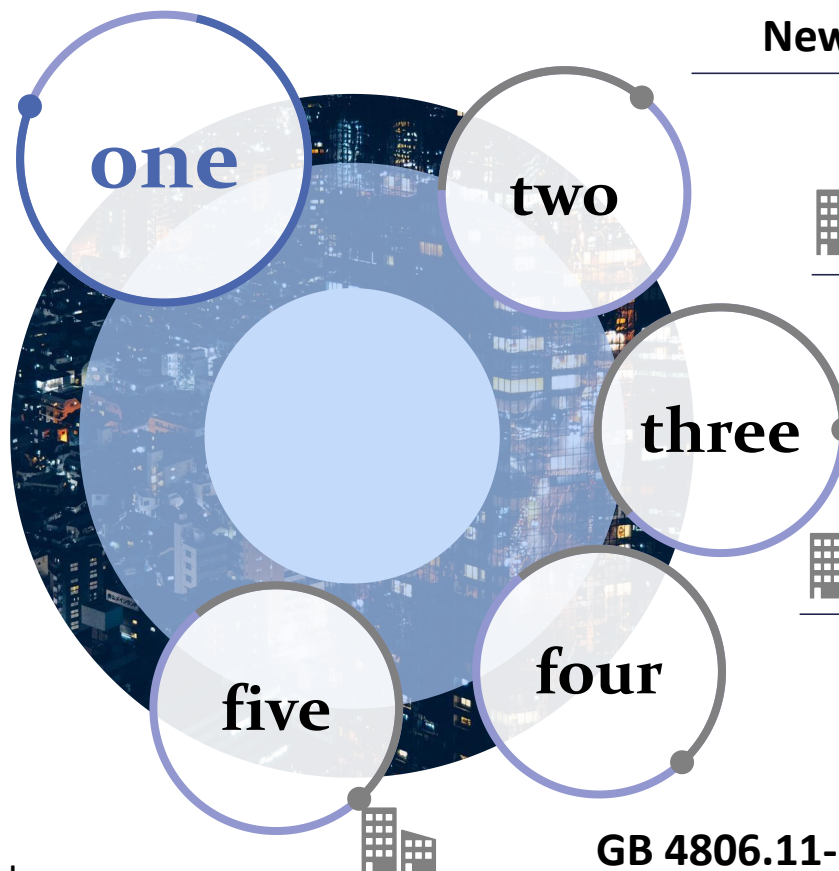
Compliance Workflow



Positive list of FCM

GB 9685-2016 Use of Additives

- Appendix A.1 permitted additives for plastic FCM
- Appendix A.2 permitted additives for **paints and coatings** for food contact use
- Appendix A.3 permitted additives for **rubber** FCM
- Appendix A.4 permitted additives for **printing inks** for food contact use
- Appendix A.5 permitted additives for **adhesives** for food contact use
- Appendix A.6 permitted additives for **paper and board** for food contact use
- Appendix A.7 permitted additives for **other FCM** such as **silicon rubber**
- GB 2760 Table A.2 **Food Additives** Permitted for Use in Various Kinds of Food in Accordance with GMP



NHC Announcements for New Food-related Products



GB 4806.6-2016 Plastic resin

- Appendix A.1 Permitted resins and specifications



GB 4806.10-2016 Coating

- Appendix A.1 permitted raw materials of coatings and their specifications



GB 4806.11-2016 Rubber

- Appendix A.1 permitted raw materials of rubber and their specifications

Finished Product Testing

Take PET Plastic Cup as an Example

GB 4806.7 Plastic

Testing
Program

- ◆ **Sensory requirements**
- ◆ **General physicochemical testing**
 - Overall migration
 - Potassium permanganate consumption
 - Heavy metal (as Pb)
 - Decolorization test (limited to products with added colorants)。
- ◆ **Other physicochemical compliance testing**

The specific migration limit (SML), total specific migration limit [SML(T)] and residual quantity of monomers and additives meet the requirements of relevant regulations:

 - Specific migration limit (as Sb)
 - Total specific migration (as terephthalic acid)

.....

Finished product Testing

- Specifies the selection of the area-to-volume ratio
- Specifies the selection of food simulants;
- Specifies the selection of specific migration test temperature and time, as well as Temperature Rise Acceleration Test Conditions for Specific Migration
- Specifies the selection of the total migration test temperature and time;
- Specifies the compliance determination of reusable food contact materials and articles :

Its compliance shall be checked based on the determination result in the third test; For the food contact materials that specific migration amount cannot be detected, the compliance judgment shall be carried out based on the determination result of the first migration test.

Chemical Solvent substitutes for fatty food simulants

95% (volume fraction) ethanol, n-hexane, n-heptane, and isooctane.

GB 31604.1 General Rules for Migration Test of FCM and Articles

Food Category and Food Simulants

Food Category	Food Simulants
Water-based food, content of ethanol \leq 10% (volume fraction) Non-acidic food (pH \geq 5) ^a Acidic food (pH $<$ 5)	10% (volume fraction) ethanol or water 4% (volume fraction) acetic acid
Alcoholic drink, content of ethanol $>$ 10% (volume fraction) Content of ethanol \leq 20% (volume fraction) ^b 20% (volume fraction) $<$ content of ethanol \leq 50% (volume fraction) ^c Content of ethanol $>$ 50% (volume fraction)	20% (volume fraction) ethanol 50% (volume fraction) ethanol Actual concentration or 95% (volume fraction) ethanol
Fat and food with fatty substances on the surface	Vegetable oil ^d

Declaration of Compliance (DoC)



塑料食品接触材料供应链责任及符合性声明

行业指南

2017年04月18日

中国食品工业协会食品接触材料专家委员会



Declaration of
Compliance
(DoC)

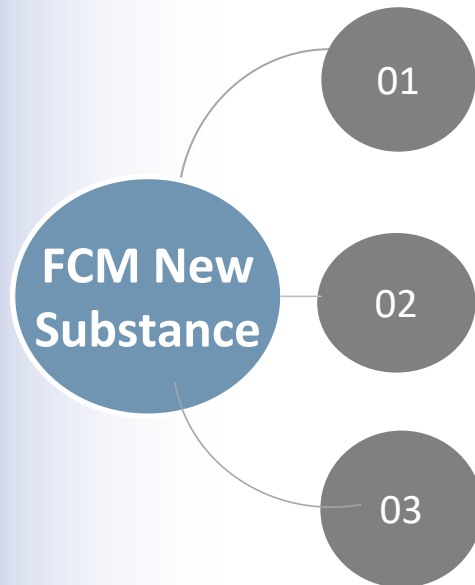
CONTENT (GB 4806.1)

- Corresponding regulations and standards
- List of substances with restrictive requirements and their restrictive requirements
- Compliance with overall migration limit (only finished products) etc.

Function

- Deliver information
- Clarify the responsibilities of all links of supply chain (Definition of responsibilities)
- Traceability
- Supervision need (Documents to be provided for customs clearance inspection and the spot check by State Administration for Market Regulation)

New food Contact Substance Application



Food packaging materials, containers and additives that have **not been listed** in the national food safety standards or NHC Announcements;

Food packaging materials, containers and additives that are to **be used more widely or in greater quantities**;

New materials and new additives in food production and operation tools and equipment that directly contact food.

New food Contact Substance Application

Required Materials

NO.	Materials	New Substance	Expand the scope of use or usage
1	Application form	√	√
2	Physicochemical property	√	
3	Technical necessity, purpose and use conditions	√	√
4	Manufacturing Technique	√	
5	Quality specification requirements, test methods and test reports	√	
6	Toxicological safety assessment data	√	√
7	Migration and/ or residue, estimated dietary exposure and its assessment method	√	√
8	Materials or supporting documents of permitted usage at home and abroad (it is allowed in at least 2 foreign countries)	√	
9	Other information that may assist in the evaluation	√	
10	Scope of use and usage	Only for new additives	√

New food Contact Substance Application

Toxicity Experiment

No.	Testing items	Volume of migration (mg/kg)			
		≤ 0.01	0.01-0.05	0.05-5.0	5.0-60
1	Ames Test		√	√	√
2	Bone marrow cell micronucleus test		√	√	√
3	In vitro mammalian cell chromosome aberration test or in vitro mammalian cell gene mutation aberration test		√	√	√
4	90-day oral subchronic toxicity in rats			√	√
5	acute oral toxicity				√
6	Reproductive and developmental toxicity				√
7	Chronic oral toxicity				√
8	carcinogenicity test				√
High-molecular polymers (average molecular weight greater than 1000 Daltons) should provide toxicological safety assessment data for each monomer					

New food Contact Substance Application

Application Procedure

Organization

NHC

CFSA

CFSA

NHC

Period

5 working days

60 working days

Procedure

Accept



Technical evaluation

Pass



Draft for comments



Approval announcement



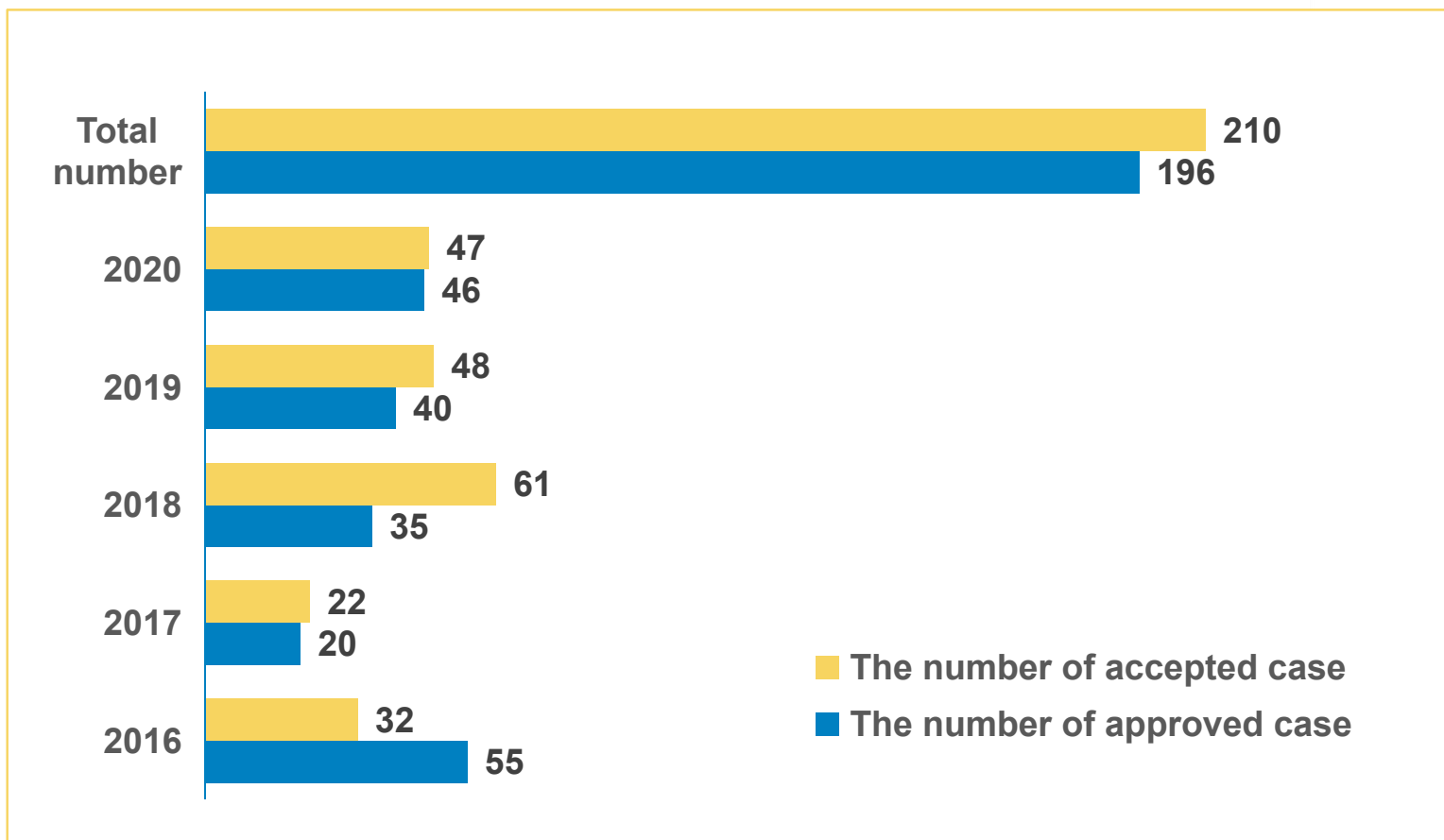
Update additional materials



New food Contact Substance Application

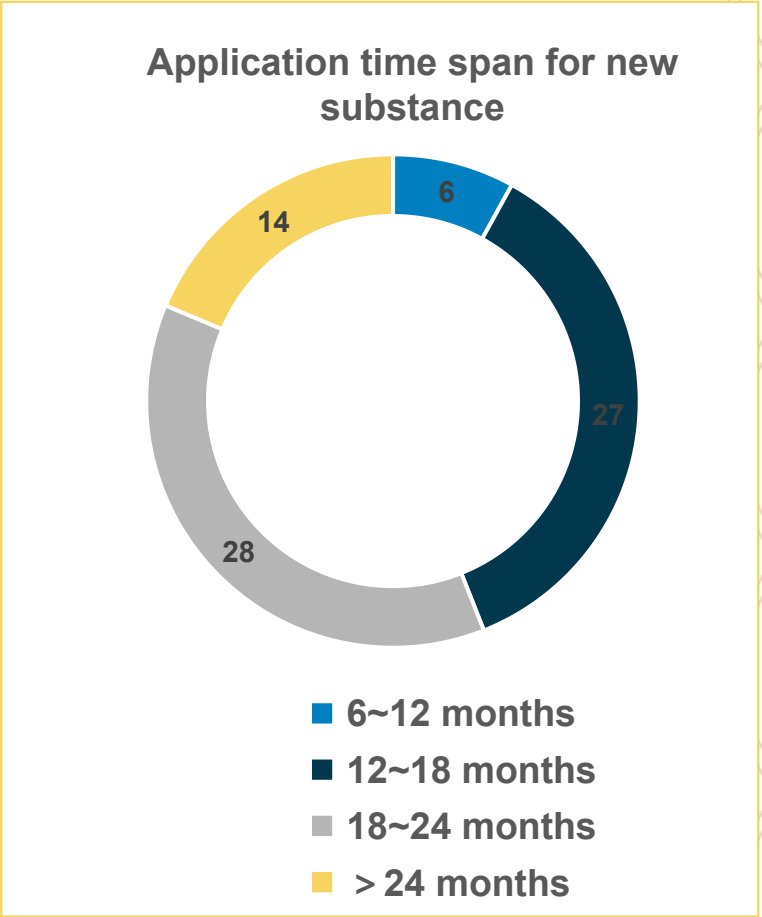
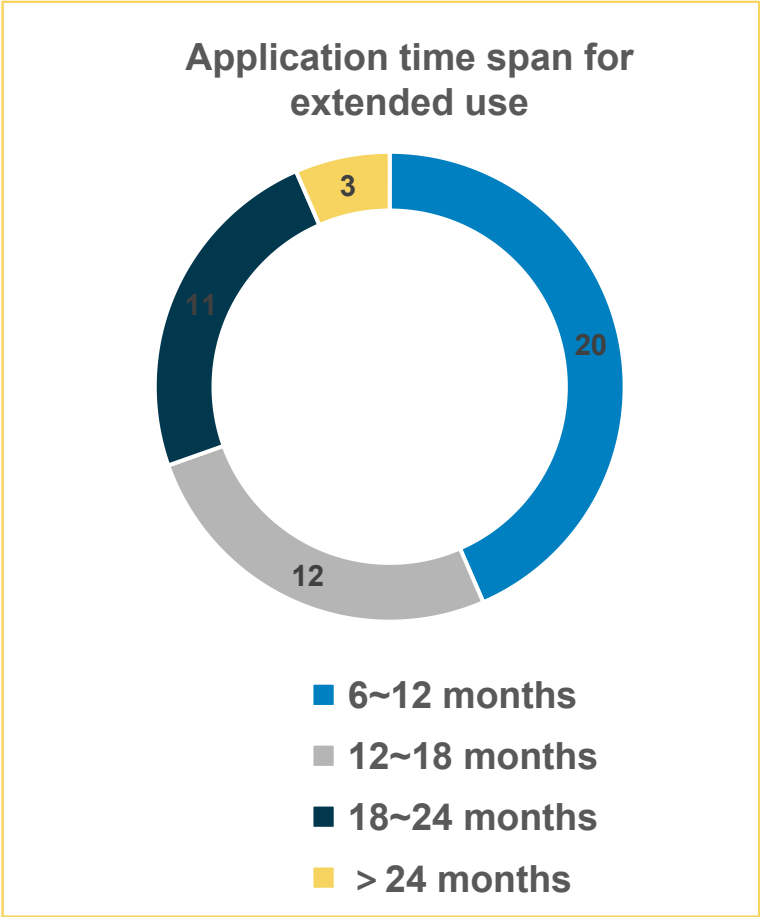
New food contact substance application: the number of accepted case VS the number of approved case

(2016-2020)



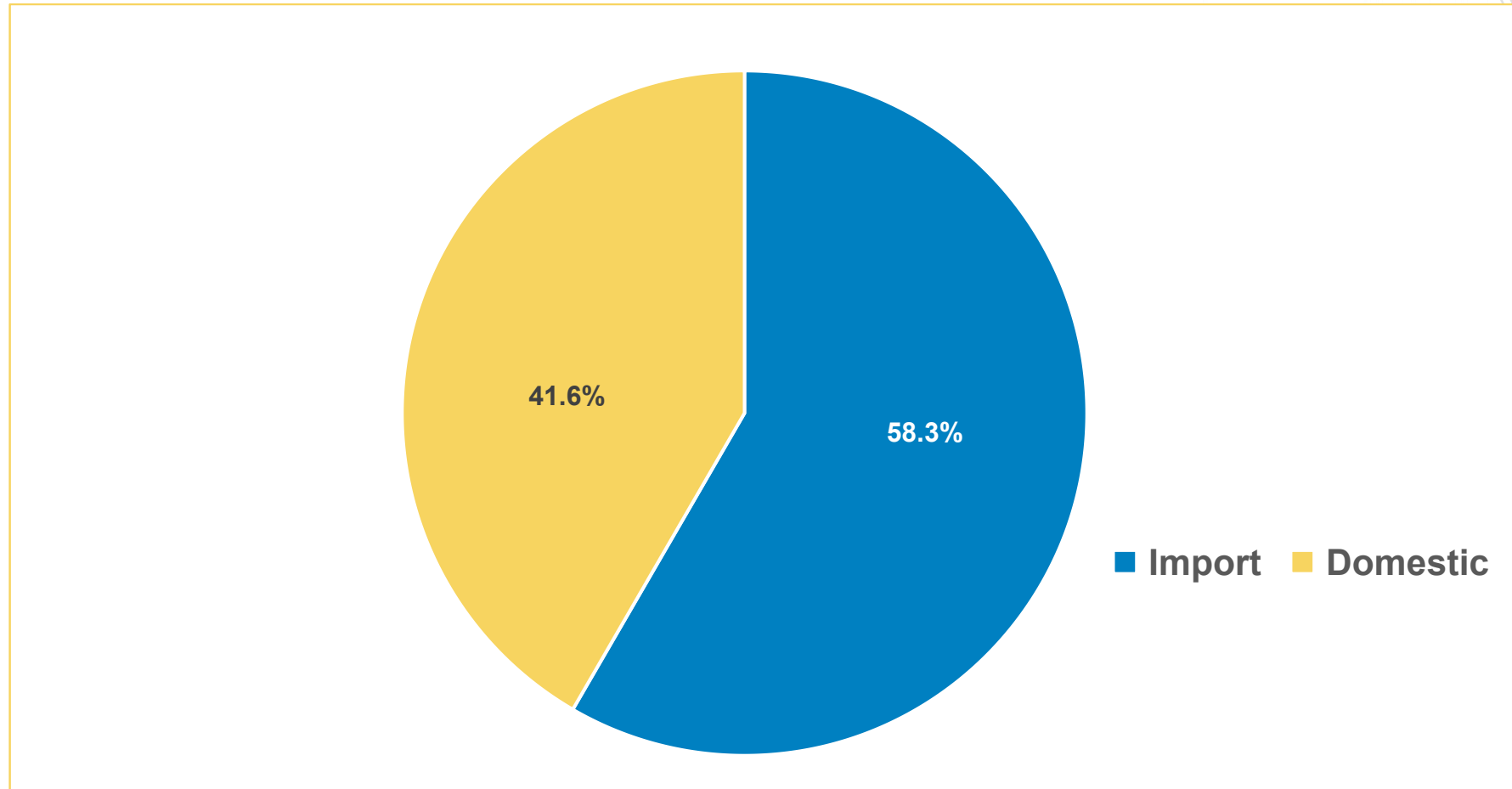
New food Contact Substance Application

Application time span for extended use and new substance (2018-2020)



New food Contact Substance Application

Import VS Domestic



Our Services



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Global Product Compliance (GPC)



compliance@gpcregulatory.com



+46 46 2114615



IDEON, Beta 5, Scheelevägen 17, 22363
LUND, SWEDEN