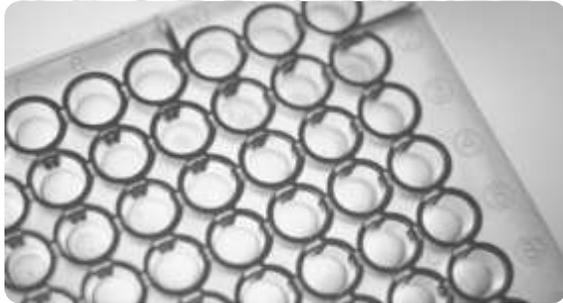


A Road Map to Food Contact Materials and Articles Regulations in China



Jim Mo

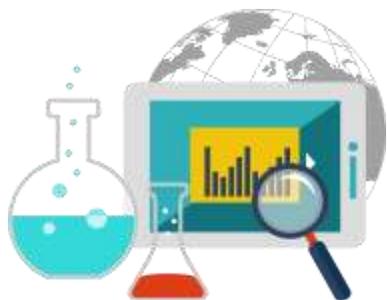
Business Development/Regulatory Consultant

CIRS Group USA Inc.

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CIRS Services



Chemical Registration



Global GHS



Food and Food-related Products



Cosmetics



Pesticides and Biocides

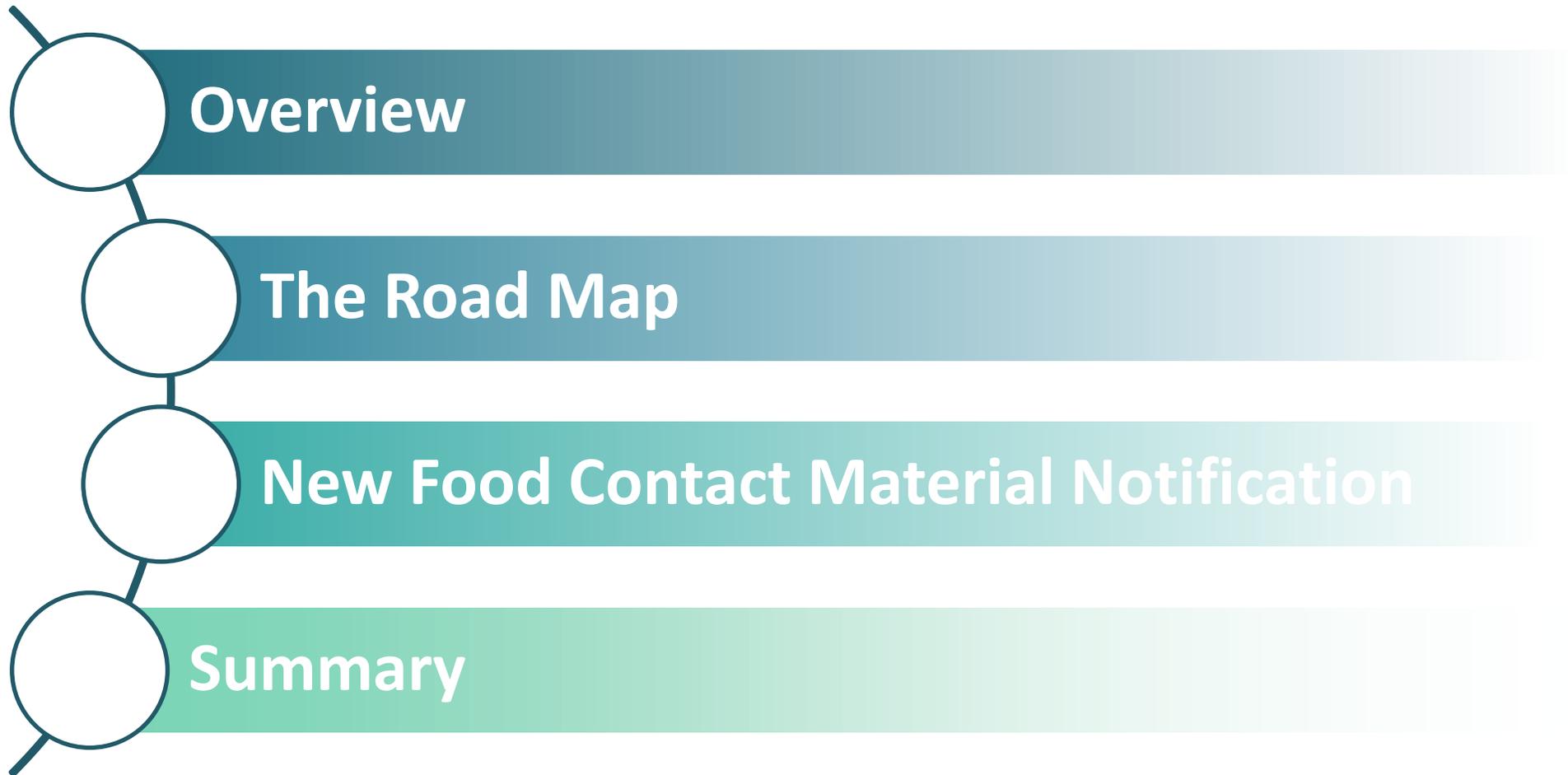


Medical Devices

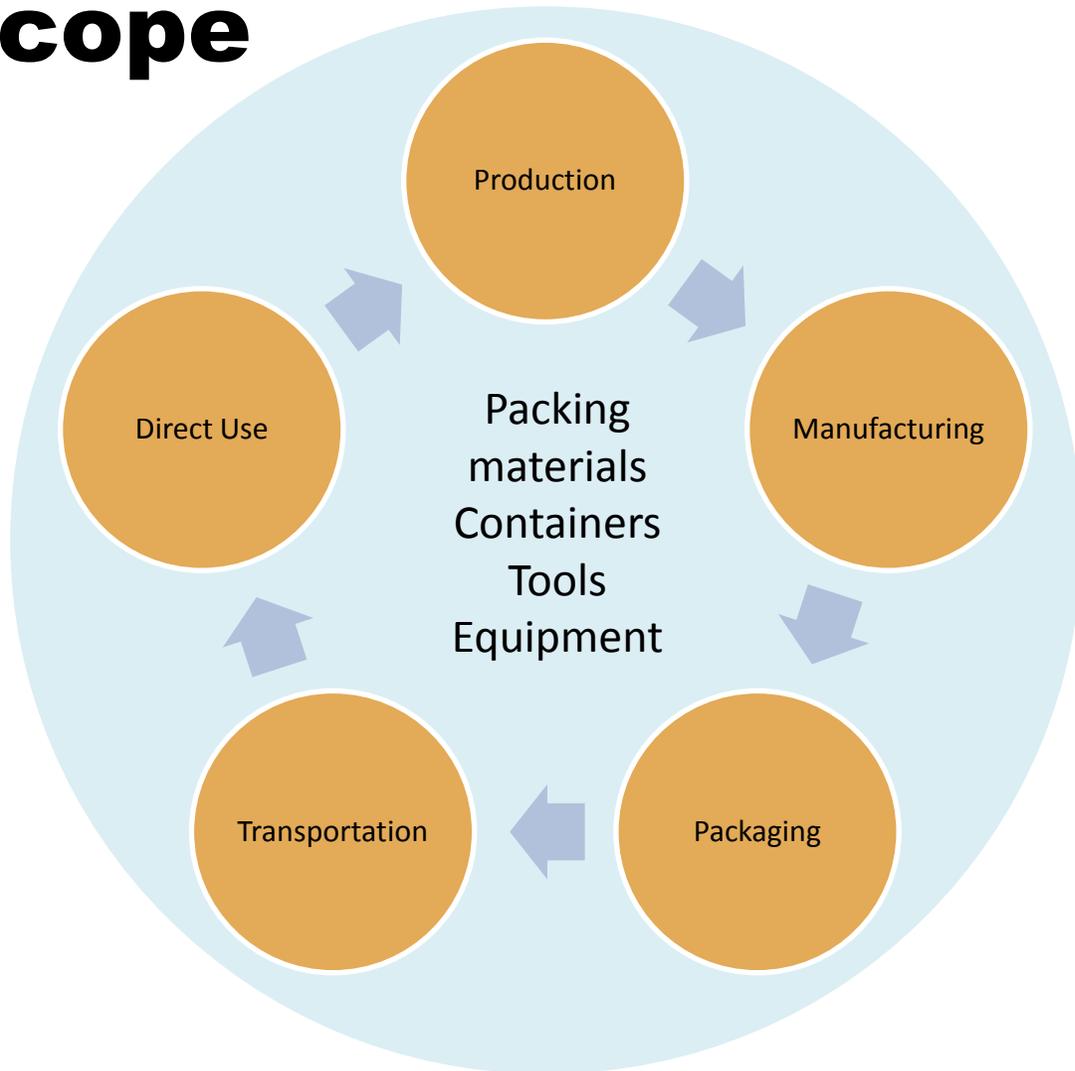
Food Contact Material Services

- ❖ New food contact material notification
- ❖ FCM testing
- ❖ FCM DoC
- ❖ FCM consultation and training
- ❖ FCM regulation monitoring and alert





Scope



Related



a. Already or are to be in direct contact with food or food additives

b. Components are likely to migrate into food or food additives

Overview

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Framework



- Built on standards
- Old standards are old...
- Inefficiently revised

But

- Improvement has appeared
- Forming regulation framework
- Still powerful
- Risk assessment catching up

Overview

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Framework



*“Standard” based!
Have Positive lists*

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Framework



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Influence on food industry

- Supervision
 - AQSIQ & SAMR
 - Random inspection
 - Enforcement result
 - Risk alert
- Enforcement
 - Recall or destroy

Overview

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About Your Products and Yourself

- Categorizing FCM
 - Raw material
 - Additive
 - Finished product or article
- Identifying yourselves
 - Manufacturer
 - Distributor

Overview

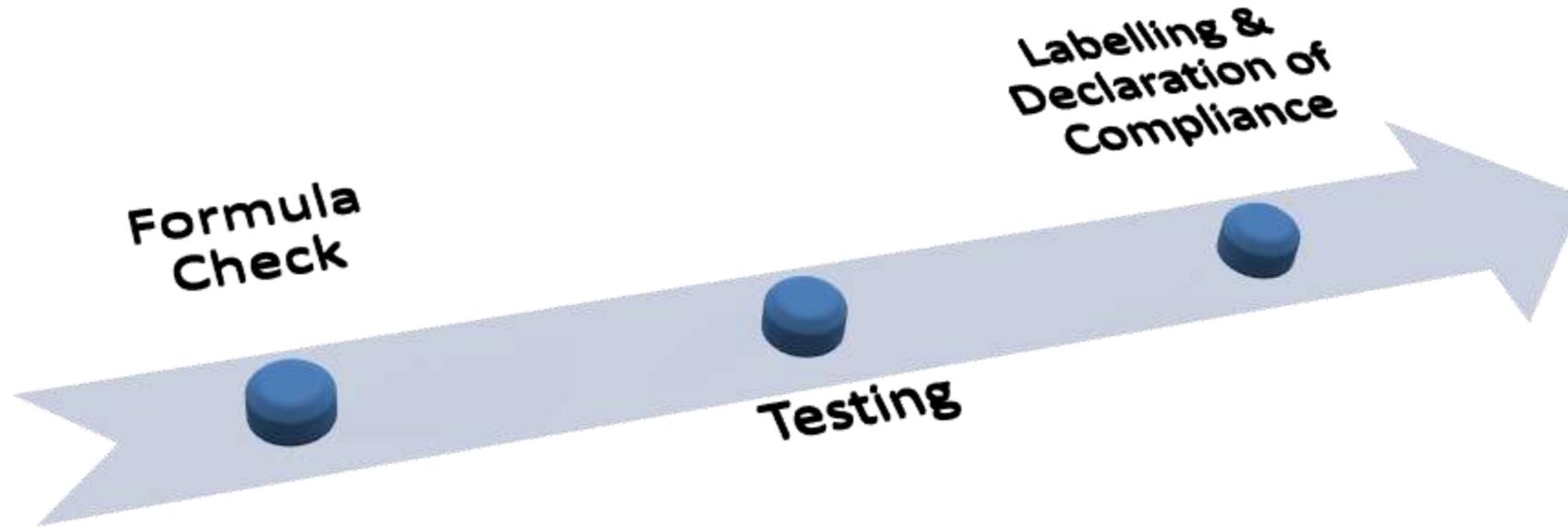
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3 Steps



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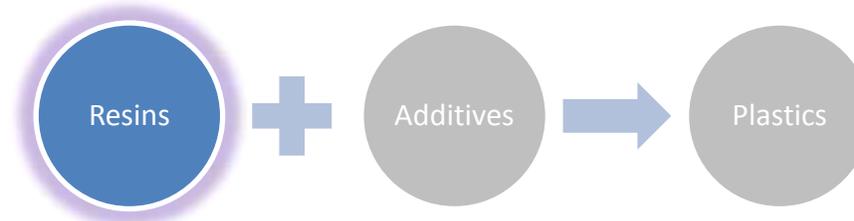
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Summary



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Formula Check



- Positive list - GB 4806.6-2016 Food Contact Plastic Resins

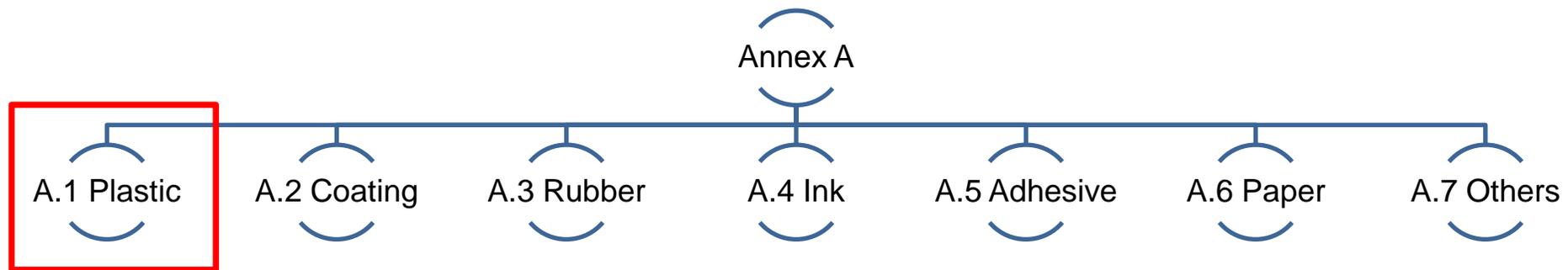
Table A.1 List of Approved Plastic Resins and Usage Requirements (sample)

No.	Name	CAS No.	Common category name	SML/QM (mg/kg)	SML(T) (mg/kg)	SML Grouping number	Other requirements
3	NYLON 6/12	26098-55-5	PA	2.4 (1,6-HEXANE DIAMINE :SML)			

Formula Check



- Positive list – GB 9685-2016 Use of Additives in Food Contact Materials.



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Formula Check



Table A.1 List of Approved Additives Used in Food Contact Materials and Usage Requirements

FCA number	Name	CAS No.	Application and max usage	SML/QM (mg/kg)	SML(T) (mg/kg)	SML Grouping number	Other requirements
FCA0047	Ethylene Glycol	107-21-1	PE, PP, PS, AS, ABS, PA, PET, PC, PVC, PVDC, UP: appropriate amount according to production requirement		30	2	

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Formula Check



Sometimes **GB 9685 – 2016** is not the only standard applied...

- ✓ Mixtures of substances listed in Tables A.1 (no reaction)
- ✓ Substances listed in Table A.2 of GB 2760-2014 (no effect to property of food)
- ✓ Some salts and crystalline hydrate in Table A.1 of GB 2760-2014
- ✓ The approved polymers (molecular weight higher than 1000 Dalton) can be used as food contact additives in the same approved scope.

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Testing



WHAT Properties should be tested?

GB 4806.6 *Food Contact Plastic Resins*

▶ GB 4806.7 *Food Contact Plastic*

GB 9685-2016 *Use of Additives in Food Contact Materials*

HOW to carry out testing?

GB 31604.X *Testing Migration Level of XX in XX*

GB 5009.156 *Pretreatment of Food Contact Material for Migration Level Test*

Overview

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Testing

Basic required tests in GB 4806.7

Required tests	Requirements	Test method
Sample senses	Normal color, etc.	N/A
Soaking solution	No odor, etc.	N/A
Overall migration	$\leq 10\text{mg}/\text{dm}^2$	GB 31604.8
Overall migration for infant FCM	$\leq 60\text{mg}/\text{kg}$	GB 31604.8
The consumption of Potassium permanganate	$\leq 10\text{mg}/\text{kg}$	GB 31604.2
Heavy metal (Pb)	$\leq 1\text{mg}/\text{kg}$	GB 31604.9
Color stability test for FCM with colorant	Negative	GB 31604.7

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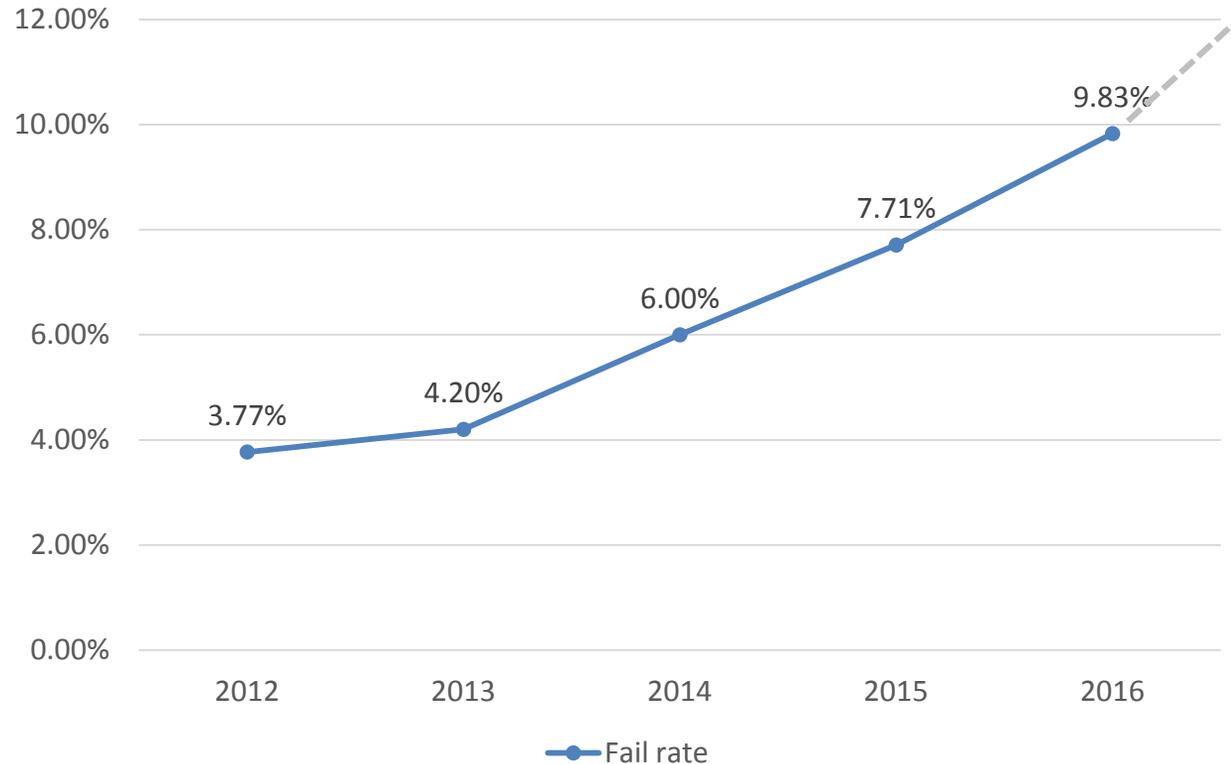
Summary



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Imported food contact material Inspection Report in released in 2016

Increasing Fail Rate of Imported FCM 2012-2016



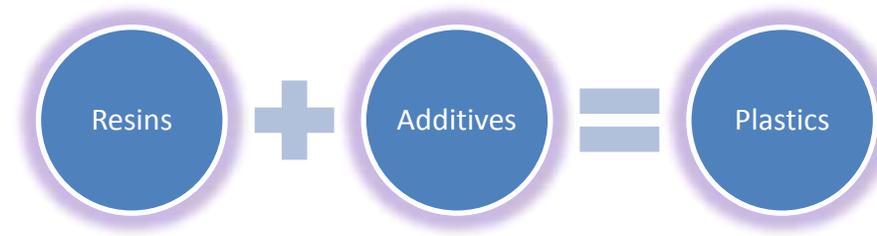
- Inspected by AQSIQ at custom
- Ceramics, **plastics, metals, papers** and other materials (mostly **glass**)
- Highest 2.71% (plastics) , lowest 0.66% (Ceramics)

*Report of 2017 and 2018 still not available.

Source: *Quality of Imported Food Contact Material Product in 2016 by SAMR*



Declaration of Compliance & Labelling



The major requirements of GB 4806.1-2016 General Safety Requirements of Food Contact Materials that apply to **ALL** types of food contact materials are listed as follows:

- Basic Requirements
- Restrictions
- Compliance Principle
- Test Methods
- Traceability
- **Product Information**

Overview

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Declaration of Compliance & Labelling

What's required for labelling?

According to GB4806.1:

- Product name;
- Product material;
- Name, address, and contact information of manufacturer and/or distributor;
- Production date;
- Shelf life if applicable;
- Instructions if applicable;
- “food contact use”, or print/past with spoon & chopsticks logo as following:



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Declaration of Compliance & Labelling

What about Declaration of Compliance (DoC)?

- A crucial document to acquire clearance at custom
- One of **the most neglected documents** in dossier
- Section 8 of GB 4806.1-2016
- Industrial Guidance by China National Food Industry Association (CNFIA)

Overview

The Road Map

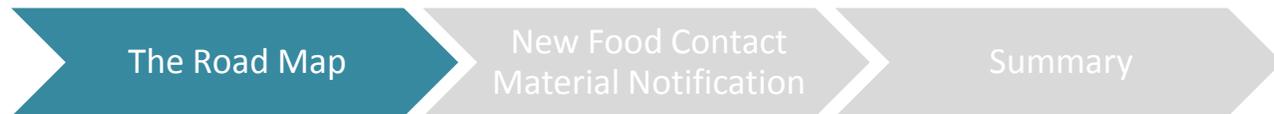
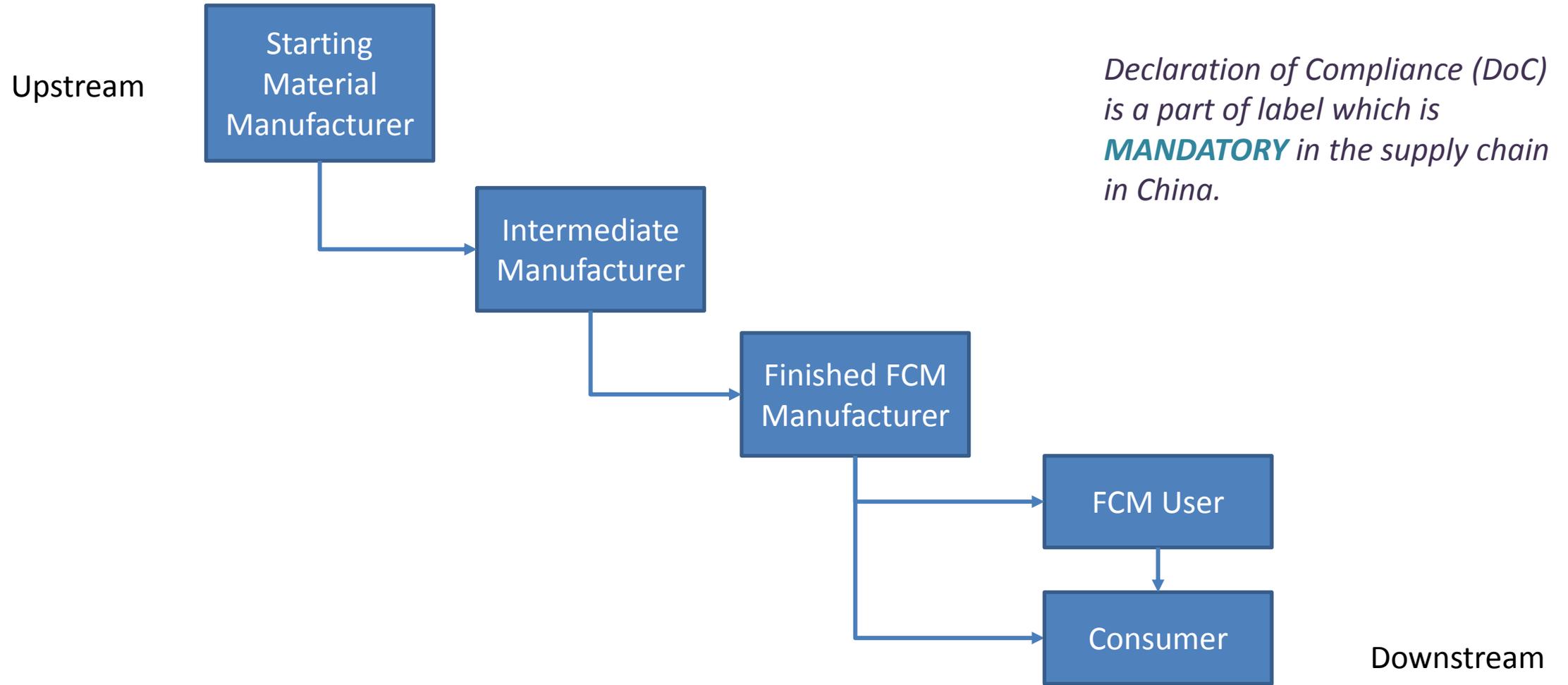
New Food Contact
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Declaration of Compliance & Labelling



Declaration of Compliance & Labelling

As a finished plastic product, the DoC is suggested to issue like below:

Title: Declaration of Compliance (Product A)

Disclosed information	Note
Product Name	
Material Information	Supplier vs importer vs distributor ← Confidentiality?
Manufacturer	
Contact Info of Manufacturer	
Declarant	
Contact Info of Declarant	
Condition of Use	
Regulatory Compliance	
Proof of Compliance	
Disclaimer	

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What if you have something new?

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Scope

In accordance with *Food Safety Law* of the People's Republic of China, company which plan to:

- 1. Use new substances (including new food contact resins and new food contact additives),***
- 2. Apply existing food contact resins or additives in a larger scope,***

shall submit the related safety assessment to NHC.

Legislative

Food Safety Law

<GB 4806.1-2016>

<Administrative Measure on New Food Related Products>, Notice 25, 2011, NHFPC

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Required Documents

1. Application form
2. Physicochemical property
3. Technical necessity, application & use condition
4. Manufacturing technique
5. Qualification specification requirements, test methods and test report
6. Toxicology safety assessment documents
7. Migration test or residual test, dietary exposure, and analytical methods
8. Other document to support the use at overseas
9. Other supplementary documents
10. Power of attorney (when the registration application run by entrusted agencies)
11. Certifying documents issued by government authorities or industry associations in the exporting country (region) of origin, proving that the new food contact substance is allowed to manufacture or sell in the country (region)
12. Certifying documents issued by government authorities or industry associations in the producing country (region) of origin, proving that the new food contact substance manufacturer has been examined or certificated

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Time Frame

Notification Procedure	Time line
Feasibility analysis	5-7 workdays
Available documents integration by client	Case-by-case
Document gap analysis	Usually within 1 month
Qualification specification test	14 workdays
Migration test	15-60 workdays
Toxicity tests (if necessary)	5-10 months
Dossier preparation and submission	1 month
Application acceptance	5 workdays
Technical review	60 workdays
Re-evaluation if necessary(supplement dossiers)	1 year (Usually can be completed within 4 months)
CFSA issues the draft comments for approval	1 month
NHC makes the final approval decision	Within 20 workdays
Total	11-25 months

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Summary

- More standards to be developed
- General supervision and enforcement levels are likely to go up in the near future
- Importance of DoC
- Unnecessary disclosure of confidential business information can be avoided
- Check if it's necessary to notify NHC about your FCM

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Q&A

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