



EU-Asia Cooperation on (Phyto-) Sanitary and Food Safety Regulation

The general and specific requirements
for compliance of FCM with
Regulations (EC) No 1935/2004, and Regulation
(EC) No 2023/2006

Milada Sycova

Seminar on FCM, Bangkok, 26st June 2023



Contracting Authority
Regional Team FPI

Contract Number
PI/2019/409-971

Contractor





Objective of the project

To improve conditions for the EU food and drink industry to access the markets of target countries as well as target countries



Purpose of the Project

- a) Strengthen the regulatory dialogue between the EU and targeted Asian governments on (phyto-) sanitary and food safety-related issues and establish an avenue for cooperation between the administrations and EU Commission, Member States and industry together.
- b) Ensure the respect of the international standards on regionalisation and regulatory harmonisation in Asia, and agree on the recognition of regionalisation measures taken by the EU to maintain trade in the event of an animal disease outbreak.
- c) Promote the acceptance of listing or pre-listing establishments upon guarantees provided by the exporting government and without prior inspection by the importing party (so-called pre-listing).
- d) Promote market access for European stakeholders, through the identification and dissemination of market information on Asian food and drink markets in targeted countries.



Scope of FCM legislation

1. Active and intelligent materials and articles
2. Adhesives
3. Ceramics
4. Cork
5. Rubbers
6. Glass
7. Ion-exchange resins
8. Metals and alloys
9. Paper and board
10. Plastics + recycled plastics
11. Printing inks
12. Regenerated cellulose
13. Silicones
14. Textiles
15. Varnishes and coatings
16. Waxes
17. Wood

Listed in
Annex I
Regulation
1935/2004

Specific measures
(directives, regulation)
on EU level

In the absence of specific
measures
Member States may
adopt National provisions

Combination of these materias



FRAMEWORK REGULATION (EC) No 1935/2004

GMP REGULATION (EC) No 2023/2006

SPECIFIC MEASURES (Article 5(i))

Materials:

- Ceramics
- Regenerated cellulose film
- Plastics
- Recycled plastics
- Active and intelligent Materials

Substances:

- Nitrosamines
- Epoxy derivates: BADGE, BFDGE, NOGE
- Bisphenol A in plastic and varnished and coated FCM

Import controls:

- Melamine kitchenware
- Polyamine kitchenware





Underlying Principle: SAFETY

Article 3 Regulation
1935/2004

General
safety
requirements

- Any material or article intended to come into contact with food directly or indirectly **must be manufactured using GMP so that substances are not transferred to food** in quantities large enough:
- to endanger human health or
 - to bring about an unacceptable change in the composition of the food or
 - a deterioration in its organoleptic properties (taint)



Traceability

Article 17
Regulation
1935/2004

appropriate
system at all
stage

- **Control, recall of defective** products, consumer **information**, and the attribution of responsibility.
- Business operators must have in place **systems** and **procedures** to allow identification **from which** and **to which** materials or articles.
- The information must be made available to the **competent authorities** on demand.
- The **materials** and **articles** on the market in EU must be **identifiable** by an appropriate system which allows their traceability by means of relevant **labelling, documentation** or information.
- The **labelling** details of Article 15 (**materials not yet** in contact with food) shall comprise adequate labelling or identification conferring **traceability** on the material or article



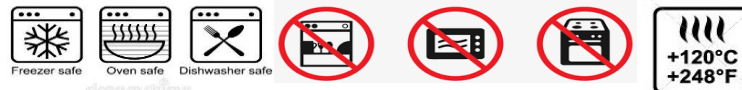
Labelling



Article 15 Regulation 1935/2004

Materials and articles (not already in contact with foodstuffs) must be accompanied by:

- a) the words „for food contact“, or a specific indication as to their use (e.g. soup spoon), or a notice showing the symbol*
- b) and, if necessary, any specific instructions for safe use,



- c) and trade name and address or registered office of supplier in EU
- d) and adequate labelling/identification for traceability

Detailed rules laid down for implementation

*Point a) is not mandatory for FCM „clearly intended to come into contact with food“



b) Retail trade in materials and articles shall be prohibited if this information is not given in a language easily understood by purchasers.

Information shall be conspicuous, clearly legible and indelible



Declaration of compliance

Article 16
Regulation
1935/2004

all materials and articles
have to be accompanied by a
written declaration stating that
they comply with the rules
applicable to them

Annex I
List of groups of materials and articles
which may be covered by specific measures

EC Declaration of Conformity
in accordance with EN 60335-1:2004

by
of
Alpha Widget Ltd
Unit 1, West Farm, Ind. Est., Watnall, W. Midlands, B1230

in accordance with the following Directive(s):
2006/95/EC The Low Voltage Directive
2004/108/EC The Electromagnetic Compatibility Directive

I hereby declare that:
Equipment: Widget heater
Model number: Super 777
Serial Number: 001230

is in conformity with the applicable requirements of the following standards:

Ref. No.	Title	Conformity
EN 60335-1	Household and similar electrical appliances - General requirements	2002
EN 60335-2-30	Particular requirements for electric hand tools - Particular requirements for power tools	2008
BS EN 61000-4-1	EMC - Immunity - Part 4: Immunity to radio-frequency electromagnetic fields (30 MHz to 100 MHz)	2007
BS EN 61000-4-3	EMC - Immunity - Part 4: Immunity to radio-frequency electromagnetic fields (30 MHz to 100 MHz) - Immunity to radio-frequency electromagnetic fields (30 MHz to 100 MHz) - Immunity to radio-frequency electromagnetic fields (30 MHz to 100 MHz)	2007
BS EN 61000-3-2	EMC - Limits - Part 3: Limits for radio-frequency current emissions (equipment input current I_{n ≤ 16 A) - Harmonic current emissions (equipment input current I_{n ≤ 16 A)	2006
BS EN 61000-3-3	EMC - Limits - Part 3: Limits for radio-frequency current emissions (equipment input current I_{n ≤ 16 A) - Harmonic current emissions (equipment input current I_{n ≤ 16 A)	2008

I hereby declare that the equipment named above has been designed to comply with the relevant provisions of the above referenced specifications. The unit complies with all applicable requirements of the Directives.

Name: [Signature]
Position: Technical Drafter
Watnall
Watnall
1 April 2010

CE10
Document Ref. No:
1234/1001234

- Detailed DoC requirements:
- Plastics
 - Recycled plastics
 - Ceramics
 - Active and Intelligent materials
 - BPA in varnished and coatings FCM



Supporting documentation



Article 16 Regulation 1935/2004

Appropriate documentation shall be available to demonstrate such compliance. That documentation shall be made available to the competent authorities on demand.

That documentation shall contain:

- The conditions and results of testing
- Calculations including modelling
- Other analysis
- Evidence on the safety
- Reasoning demonstrating compliance.

Annex I

List of groups of materials and articles which may be covered by specific measures





Good manufacturing practice

Article 3 Regulation
1935/2004

Any material or article intended to come into contact with food directly or indirectly **must be manufactured using GMP** so that substances are not transferred to food in quantities large enough:

Legal basis

- to endanger human health or
- to bring about an unacceptable change in the composition of the food or
- a deterioration in its organoleptic properties (taint)

Annex I
List of groups of materials
and articles
which may be
covered by specific measures

Commission Regulation (EC) 2023/2006
on good manufacturing practice for
materials and articles intended to come
into contact with food





Good manufacturing practice

GMP means those aspects of quality assurance which ensure that materials and articles are consistently:
produced and controlled
to ensure conformity with the rules applicable to them and with the quality standards appropriate to their intended use

safe FCM according
article 3 regulation
1935/2004

quality assurance system means the total sum of the organised and documented arrangements made with the purpose of ensuring that materials and articles are of the quality required to ensure conformity with the rules applicable to them and the quality standards necessary for their intended use

The documentation **paper or electronic format** shall be made available by the business operator to the competent authorities at their request.

quality control system means the systematic application of measures established within the quality assurance system that ensure compliance of starting materials and intermediate and finished materials and articles with the specification determined in the quality assurance system

Rules for:
Printing inks
Recycled plastics



Plastic materials and articles

**Regulation (EU)
10/2011**

Packaging
materials

All kitchen
utensils



Specific laws for plastics, more detailed than other FCMs

Requirements include restrictions on uses & migration of substances

Positive list of:

- Monomers & starting substances
- Additives

Specifies how testing should be carried out OML and SML

Specific format for 'Declaration of compliance'





Plastic materials and articles

Regulation (EU) 10/2011

Placing on the market of plastic materials and articles

Plastic materials and articles may only be placed on the market if they:

- (a) comply with the relevant requirements set out in **Article 3** of Regulation (EC) No 1935/2004 under intended and foreseeable use; and
- (b) comply with the **labelling** requirements set out in Article 15 of Regulation (EC) No 1935/2004; and
- (c) comply with the **traceability** requirements set out in Article 17 of Regulation (EC) No 1935/2004; and
- (d) are manufactured according to **good manufacturing practice** as set out in Commission Regulation (EC) No 2023/2006; and
- (e) comply with the compositional and declaration requirements set out in **Chapters II, III and IV (DoC)** of this Regulation.



Recycled plastic materials and articles

**Regulation (EU)
2022/1616**

Priority for recycling:

25% obligatory recycled PET content in plastic beverages bottles by 2025

30% obligatory recycled PET content in plastic beverages bottles by 2030





Provides frame for :

Suitable technology = mechanical PET recycling

- Recycling scheme (Annex I)
- Novel technology (Registration)

More precise in naming:

- Technology, process, installation, facility

Registration before authorisation

Templates (CMSS, registration forms, DoCs)

Timelines

- Specific requirements for labelling
- Waste management is included – requirements, certification!

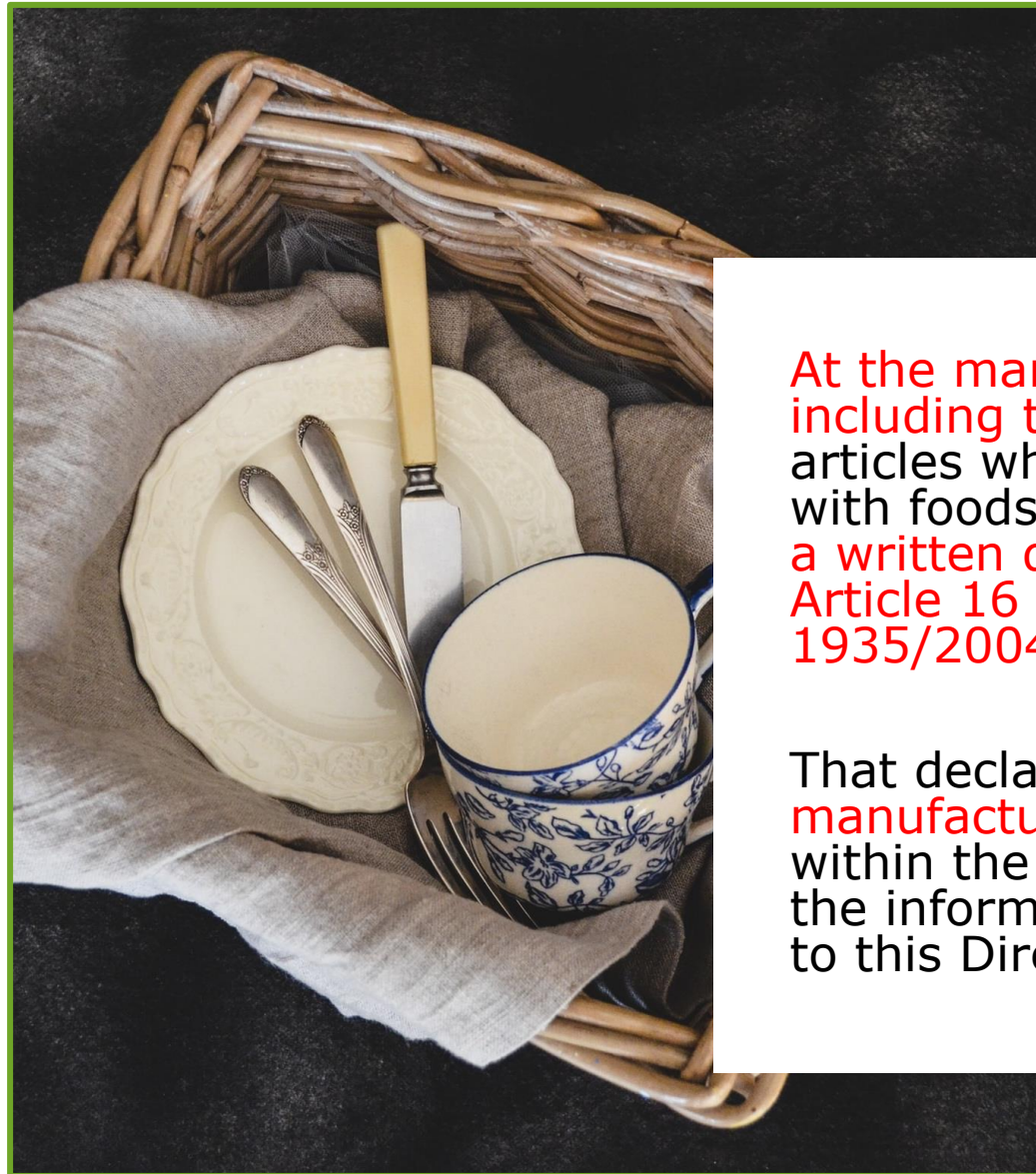


Ceramics

**Directive
84/500/EEC**

At the marketing stages up to and including the retail stage, ceramic articles which are not yet in contact with foodstuffs shall be accompanied by a written declaration in accordance with Article 16 of Regulation (EC) 1935/2004

That declaration shall be issued by the manufacturer or by a seller established within the Community and shall contain the information laid down in Annex III to this Directive.





Ceramics

Declaration of Compliance

1. the identity and address of the company which manufactures the finished ceramic article and of the importer who imports it into the Community
2. the identity of the ceramic article
3. the date of the declaration
4. the confirmation that the ceramic article meets relevant requirements in this Directive and Regulation (EC) No 1935/2004.

Supporting Documents

That documentation shall contain :

- the results of the analysis (Cd, Pb)
- the test conditions
- the name and the address of the laboratory that performed the testing.



The written declaration shall permit an easy identification of the goods for which it is issued and shall be renewed when substantial changes in the production bring about changes in the migration of Pb and Cd



Ceramics

Limits migration of metals (Pb, Cd)

Test methods

(contact with 4% acetic acid for 24 hours at 22°C)



Type of article	Lead	Cadmium
Not fillable, or height <25 mm (e.g., plates)	0.8 mg/dm ²	0.07 mg/dm ²
Articles fillable, or height >25 mm (e.g., cups)	4.0 mg/L	0.3 mg/L
Cooking Ware; Packaging/ Vessels Volume > 3L	1.5 mg/L	0.1 mg/L



Regenerated Cellulose Film (RCF)

Directive 2007/42/EC

- Applies to uncoated RCF and RCF coated with RCF or plastics
- RCF composition is restricted to listed substances
- Substances have limits on their quantity in the RCF and/or migration from RCF
- Plastic coatings, if used, must comply with law on plastics

No content for DoC



Active / Intelligent materials (AIM)

Active: intended to extend the shelf-life or to maintain or improve the condition of packaged food

Intelligent: monitor the condition of packaged food or the environment surrounding the food

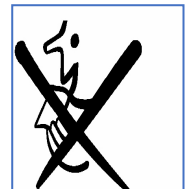
Regulation 1935/2004

- AIM must not give misleading information
- Non-edible parts (e.g. sachets) must be labelled
- Must be labelled as active/intelligent
- Extra information for active packaging that releases substances



Regulation 450/2009

- Specific detailed rules
- Active/intelligent component must be authorised by Commission, after EFSA evaluation



- Labelled
DO NOT EAT & symbol
- Requires a **declaration of compliance**



Active / Intelligent materials (AIM)

**Regulation (EC)
450/2009**

Declaration of compliance

At the marketing stages other than at the point of sale to the final consumer, active and intelligent materials and articles, whether or not they are in contact with food, or the components intended for the manufacturing of those materials and articles or the substances intended for the manufacturing of those components, shall be accompanied by a written declaration in accordance with Article 16 of Regulation (EC) No 1935/2004.

DoC:

- adequate information relative to the substances which constitute the components
- adequate information on the suitability and effectiveness of the active or intelligent material or article
- specifications on the use of the component
- specifications on the use of the material or article



Active / Intelligent materials (AIM)

Regulation (EC)
450/2009

Supporting documentation

That documentations **shall contain information:**

- on the suitability and effectiveness of the active or intelligent material or article
- the conditions and results of testing or calculations or other analysis and
- evidence on the safety or the reasoning demonstrating compliance





Nitrosamines in teats and soothers

Directive 93/11/EC

Limits release of

- N-nitrosamines: 0.01 mg/kg
- Substances that could form N-nitrosamines („N-nitrosatable substances“): 0.1 mg/kg

From elastomers and rubber

Test method: contact with saliva test solution (pH 9) for 24 hours at 40 °C





Certain epoxy substances

**Regulation (EC)
1895/2005**

Scope: plastics, coatings, adhesives

- Prohibits of 2 epoxy derivatives: BFDGE, NOGE

Sets SML for:

- Bisphenol A Diglycid Ether (BADGE) & water adducts: 9 mg/kg and
- BADGE & chlorohydrin derivatives: 1 mg/kg

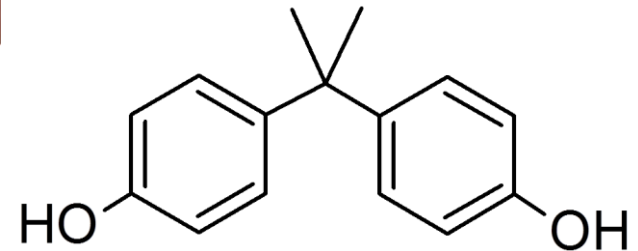


BPA (Bisphenol A)

Regulation (EU) 2018/213

Scope: coatings and varnishes made with BPA

- Sets a Specific Migration Limit (SML) for BPA from varnished and coated FCM
 - **SML of 0.05 mg/kg food**
 - **'No migration' (detection limit \geq 0.01 mg/kg food) if the FCM is for infants & young children**
- Also reduces the SML for BPA in plastics, to 0.05 mg/kg food, and bans its use in polycarbonate baby cups
- Requires a Declaration of Compliance to be given to the food industry





Declaration of Compliance for BPA in Coatings

1. The identity and address of the BO issuing the DoC
2. The identity and address of the BO which manufactures or import the coated FCM
3. The identity of the varnished or coated FCM
4. The date of DoC
5. Confirmation that varnish or coating applied to the FCM meets the restrictions laid down in art. 2 of this Regulation and the requirements set out in art, 3, 15, 17 of reg. 1935/2004
6. Specifications on the use of coated FCM, such as:
 - a) the type or types of food with which it is intended to be put into contact
 - b) the time and temperature of treatment and storage in contact with food
 - c) the highest food contact surface area to volume ratio

- DoC shall be available at all stages of manufacture, processing and distribution other than the retail stage
- DoC shall permit an easy identification of the varnished or coated materials and articles to which it applies
- It shall be renewed to reflect any changes in migration levels from varnish or coating that has been applied to FCM

Supporting
documentation 10 days



Specific regulation for import control

Regulation (EU) 284/2011

Polyamide kitchenware

- listed in REACH regulation*, no migration limit in Reg (EU) No 10/2011 Table 1 of Annex I - shall not be detectable using analytical equipment with a limit of detection of **0,002 mg/kg food or food simulant applied to each individual PAA**
- not listed in REACH regulation*, no specific migration limit specified in Reg (EU) No 10/2011 Annex I. The sum of those PAAs shall not exceed **0,01 mg/kg** in food or food simulant.

*in entry 43 to Appendix 8 of Annex XVII to Regulation (EC) No 1907/2006

Melamine kitchenware

- Analytical results demonstrating that they do not release into food or food simulants **formaldehyde** in a quantity exceeding **15 mg/kg food or food simulant**.



Release into free circulation

Prior notification of consignment

- Importers or their representatives shall notify the CA at the first point of introduction **at least 2 working days in advance** of the estimated date and time of physical arrival of consignments originating in or consigned from China and Hong Kong



Types of control

- **Documentary checks** on **all consignments** within two working days from the time of their arrival
- **Identity and physical checks**, including laboratory analysis of 10 % of consignments





Declaration to be provided for every consignment of polyamide and melamine plastic kitchenware originating in or consigned from People's Republic of China and Hong Kong Special Administrative Region, China

Name and full address (including telephone or e-mail address) of the natural or legal person issuing this declaration

Name and full address (including telephone or e-mail address) of the business operator(s) which manufacture(s) the plastic kitchenware of the consignment

Name and full address (including telephone or e-mail address) of the business operator which is responsible for the first introduction in the Union of the consignment

Identification code of the consignment:

Type and number of articles in the consignment

This consignment contains plastic kitchenware made of:

polyamide

- Analytical tests have been carried out demonstrating that the articles do not release PAA in a detectable quantity
- The detection limit of the method used is....

melamine

- The results of these tests as well as the description of the method of analysis used are attached to this document
- Analytical tests have been carried out demonstrating that the articles do not release formaldehyde in a quantity exceeding the SML of 15 mg/kg
- The results of these tests as well as the description of the method of analysis used are attached to this document

List of documents annexed confirming that the consignment meets the requirements concerning the release of primary aromatic amines or formaldehyde laid down in Directive 2002/72/EC:



Thank you for your attention!



pp.sycova@uvzsr.sk
milada.sycova@gmail.com

For more information on the project activities:



<https://eu-asia-sps.com/>
www.aets-consultants.com