

# Practical Challenges for Food Contact Materials (FCM) Stakeholders: A Regulatory View

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# Overview

- ❑ Overview of FCM controls
  - ❑ Inspection and sampling
- ❑ Challenges
- ❑ Assumptions
- ❑ Supports, for inspectors and industry



# EU Harmonised laws



## Framework Regulation (EC) No 1935/2004

**General requirements for all FCM + Mandate for specific measures**

## GMP Regulation (EC) No 2023/2006



### SPECIFIC MEASURES



#### Materials

- Ceramics *Directive 84/500/EEC*
- Regenerated cellulose film  
*Directive 2007/42/EC*
- Plastics *Regulation (EU) 10/2011*
- Recycled plastics  
*Regulation (EC) 282/2008*
- Active and intelligent Materials  
*Regulation (EC) 450/2009*



#### Substances

- Nitrosamines  
*Directive 93/11/EEC*
- Epoxy substances  
*Regulation (EC) 1895/2005*



# Other materials?

- Coatings
- Paper and board
- Glass
- Metals
- Wood
- ...



No specific EU legislation!

Must comply with:

- Framework Regulation 1935/2004
- GMP Regulation 2023/2006

[National legislation or recommendations]

Industry guidelines



# EU Laws on official controls

Regulation (EC) No 178/2002, Article 17, requires MS to undertake Official Controls

Regulation (EC) No 882/2004 details how the official controls are to be done

Regulation (EC) No 1935/2004 specifies official controls on FCMs, in line with 882/2004

Most MS have national legislation for official controls on food safety

But responsibility to comply is always with the industry!



# Controls on controls

**FVO checks**

**MS Official Controls**

**Checks by food industry**

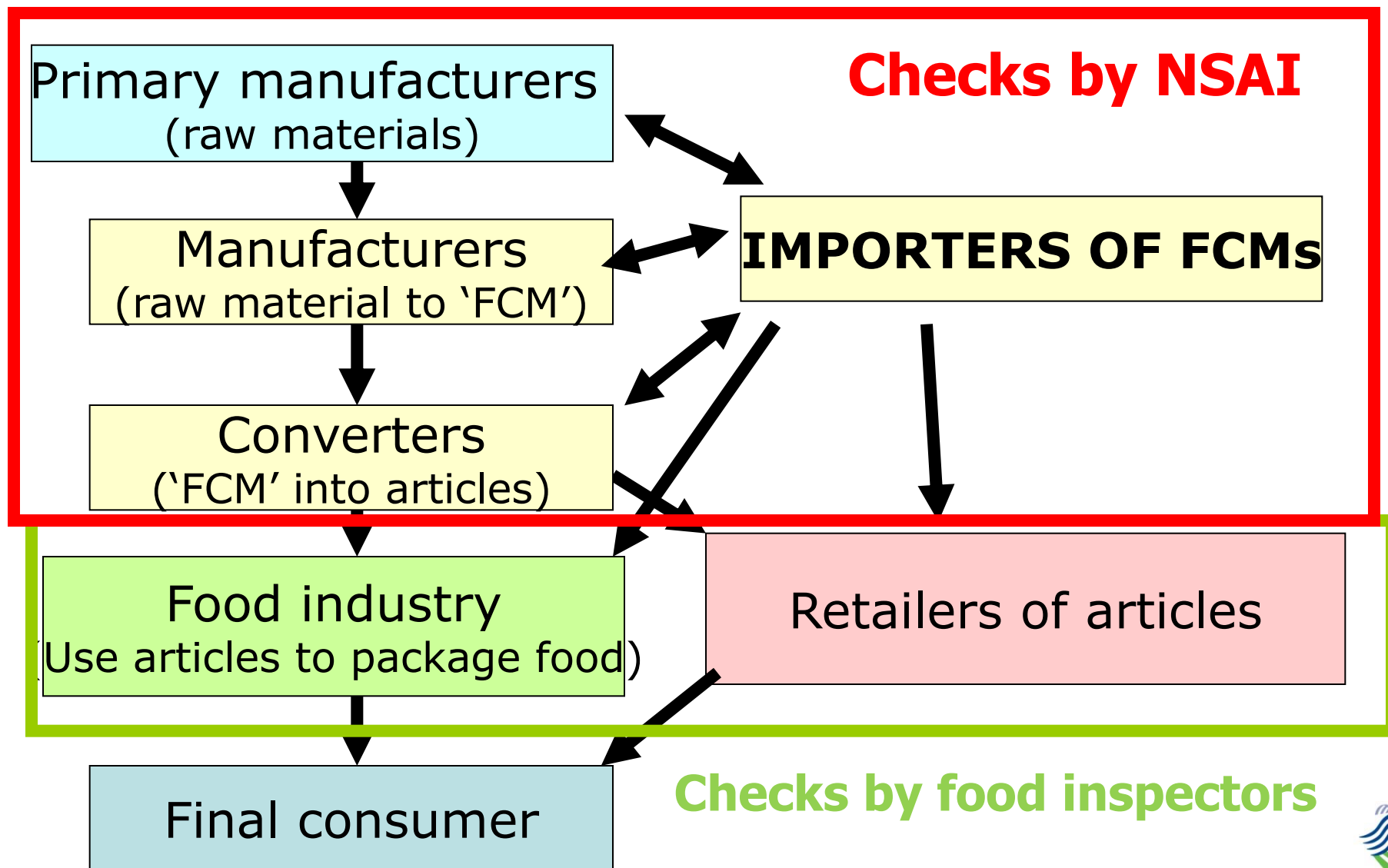
**Own checks by FCM industry**



# **CONTROLS IN IRELAND**



# Irish FCM checks





# Typical findings in FCM suppliers

## Positives

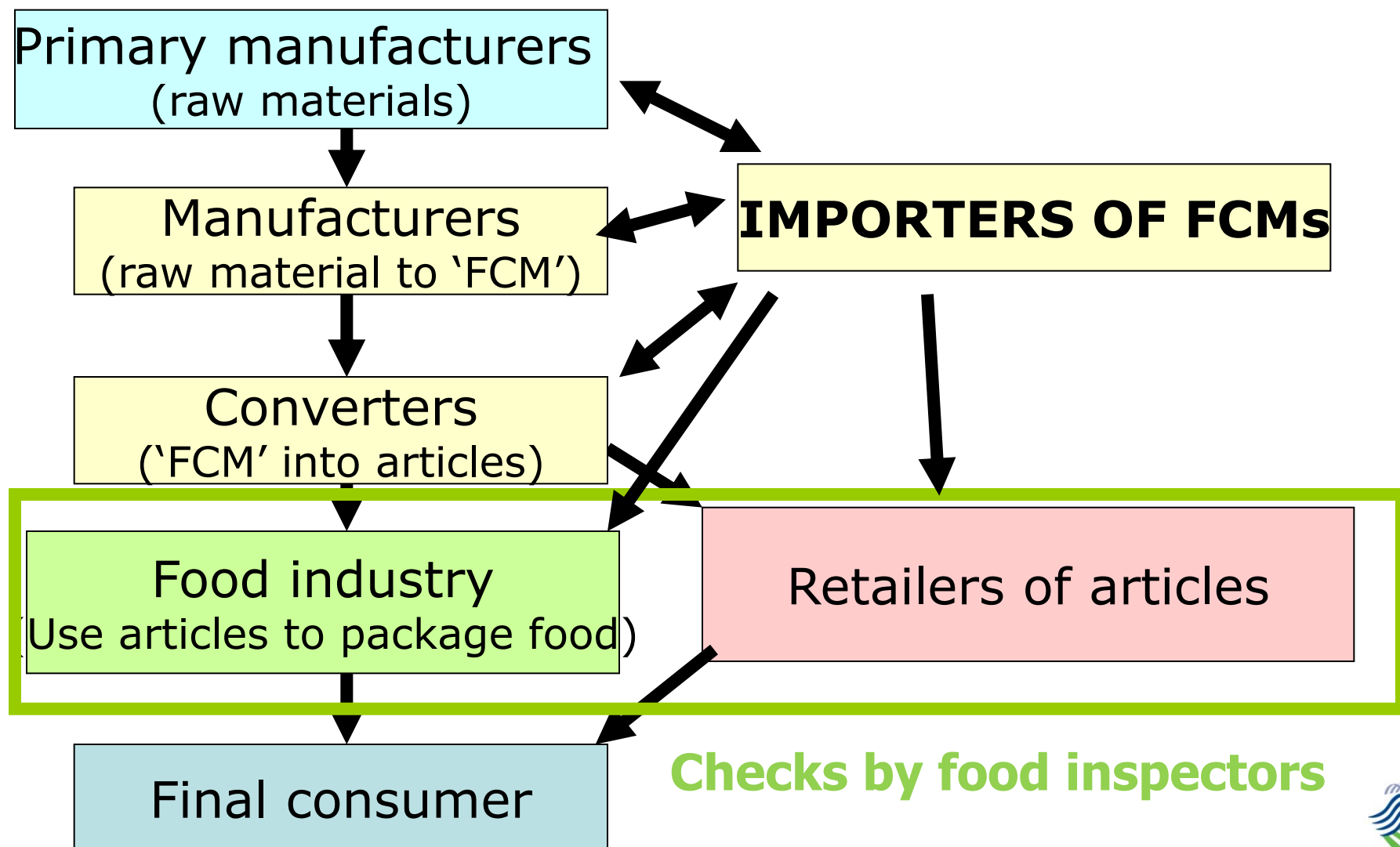
- Applying quality systems
- Having product/raw materials tested

## Negatives

- Reliant on their suppliers for expertise
- Poor declarations of compliance (where required)

Any non-compliances are followed up

# Irish FCM checks



# **SAMPLING AND TESTING**



# FCM sampling and testing

Food/FCM to be sampled	Contaminant
Nylon kitchen utensils	Primary aromatic amines
Foods in glass jars with plastics gaskets	Plasticisers
Ceramic kitchenware and metal cutlery	Heavy metals
Melamine kitchenware	Formaldehyde
Foods in printed cardboard	Photo-initiators from the inks
Plastic baby bottles	Bisphenol A

# Kitchen utensils awaiting testing



*Annual Report 2014, Public Analyst's Laboratory, Dublin*

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## Withdrawal of Black Nylon Kitchen Utensils due to migration of Primary Aromatic Amines

**Alert Notification: 2008.07**

11 September 2008

**Category II:** For Information

**Country of Origin:** China

**Product:** Nylon Kitchen Utensils

**Batch Code:** N/A



### Message

Following routine sampling and testing by the HSE, the FSAI was notified of non-conforming food contact materials (Black Nylon Kitchen Utensils) on the market. These non-compliant products exhibited excess migration of Total Primary Aromatic Amines in contravention of Commission Directive 2002/72/EC and European Communities (Plastics and Other Materials) (Contact with Food) Regulations 2007; S.I. No. 587 of 2007.

### Nature of danger

The products of concern (ladle, mashers, spaghetti server, turner, straining spoon, pasta scoop and slotted spoon) were found to exhibit excessive migration of substances known as Primary Aromatic Amines. Some of these substances are considered to be potentially harmful to human health, however any risk from the use of these utensils, is likely to be extremely small.

The implicated products were on sale in Tesco, Atlantic Homecare, Woodies DIY and other small independent retail outlets. These products have been removed from sale as they are not in compliance with food safety legislation.

Further checks on similar products are being conducted by the HSE.

The FSAI has informed the European Commission of the issue.

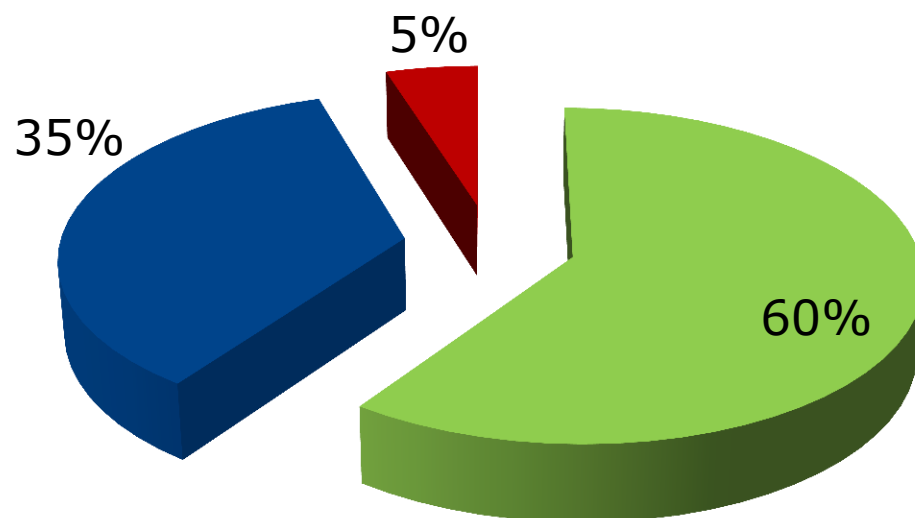
**No action required; this alert is for information only**

Brian Redahan

## Survey in 2011 on labelling, traceability, documentation supplied to food manufacturers with **Plastic Food Packaging**



# RESULTS: LABELLING REQUIREMENTS (n=204)

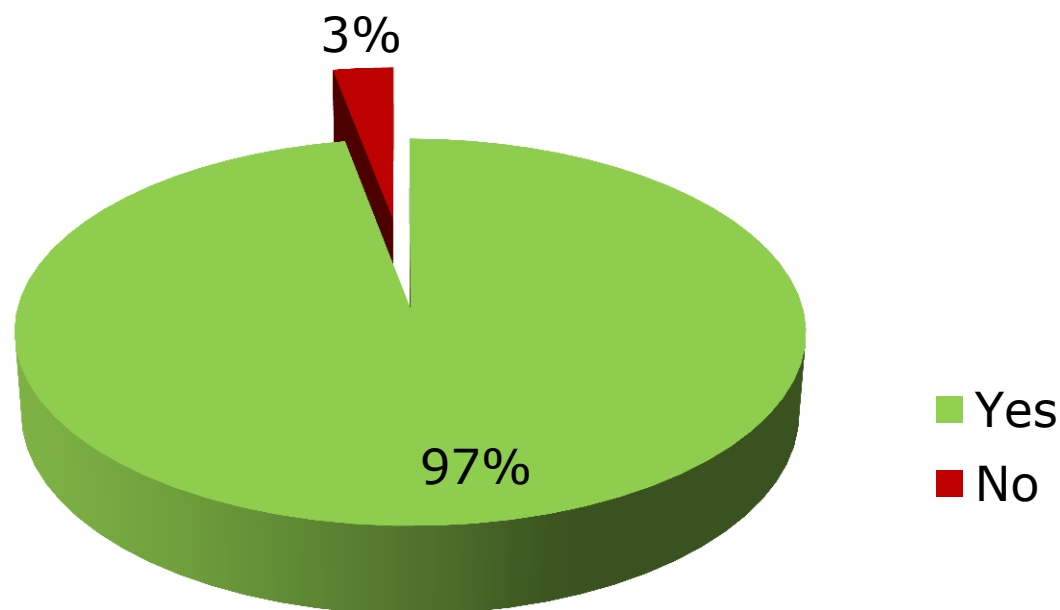


- Food contact statement present
- Clearly intended to come in contact with food
- Non compliant

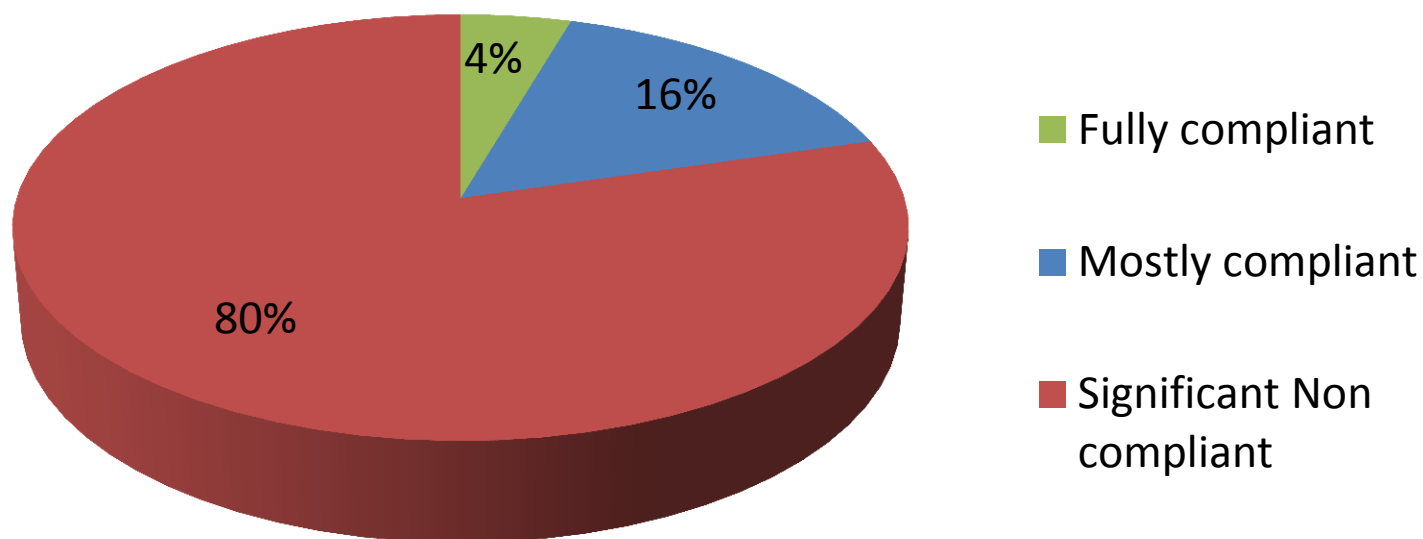




# RESULTS: TRACEABILITY TO THE PACKAGING SUPPLIER (n=204)




## Declarations of compliance for plastics: overall assessment (n=176)



But much detailed information was provided, which could be used to make a declaration of compliance in the correct format

...seems to be widespread




Startseite Kanton Zürich

Kanton Zürich  
Gesundheitsdirektion  
**Kantonales Labor** Startseite

Der Kanton Zürich nach  
Organisation

Themen A-Z

Formulare & Merkblätter



Aktuell

Über uns

Lebensmittel

Wasser

Gebrauchsgegenstände

Chemikalien

Fragen & Antworten

Medienmitteilungen

**Mitteilungen**


Veranstaltungen

Suche / Archiv

### Kunststoffhersteller liefern ungenügende Daten

30.09.2014 - Mitteilung

[« Zurück zu Mitteilungen](#)



Jede an der Herstellung von Lebensmittelkontaktmaterialien beteiligte Firma muss überprüfen (und schriftlich dokumentieren), ob die durch ihre Arbeitsprozesse eingebrachten Stoffe gesundheitlich unbedenklich sind. Die kantonalen Lebensmittelkontrollen Aargau, St. Gallen und Zürich überprüfen mit einer gemeinsamen Kampagne diese Selbstkontrolle bei neun grossen internationalen Firmen, welche den grössten Teil des Polyethylens und Polypropylens für Lebensmittelverpackungen herstellen, anhand von je einem Kunststoffprodukt.

# Challenges for official controls

- FCM has complex legislation
- Legislation changes constantly
- The packaging technology changes
- The toxicological concerns change
- Laboratory facilities limited
- Inspectors reliant on documentation
- Competing priorities (food hygiene, contaminants, additives, labelling, etc, etc)





**ASS-U-ME**



# **ASSUMPTION 1: HONESTY**



# Food 'best before' dates erased





# Food crime → food police?



# A real FCM declaration

**Declaration for Omission of Items from EU Regulation 284 / 2011**  
(laying down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from the People's Republic of China and Hong Kong Special Administrative Region, China)

I hereby declare that the following items contained within

Customs Entry No. 131EDD

Container(s) / Airway Bill No. TGHU

(list here items entered under CN code 3924 10 00 and 3924 10 00)

NYLON	WHISK	14 CARTONS
NYLON	TURNER	42 CARTONS
NYLON	MASHER	25 CARTONS

(Please tick the appropriate box)

☐ The above products are NOT food contact products (if so please state their intended use beside them)

☒ The above products DO NOT Contain Polyamide or Melamine plastic  
(defined by CN code 3924 10 00 which consist completely of polyamide or melamine or which consist of parts intended to come into contact with food that are made of polyamide or melamine. Melamine refers to formaldehyde based resins with melamine and/or urea.)

I hereby declare the above statement to be true

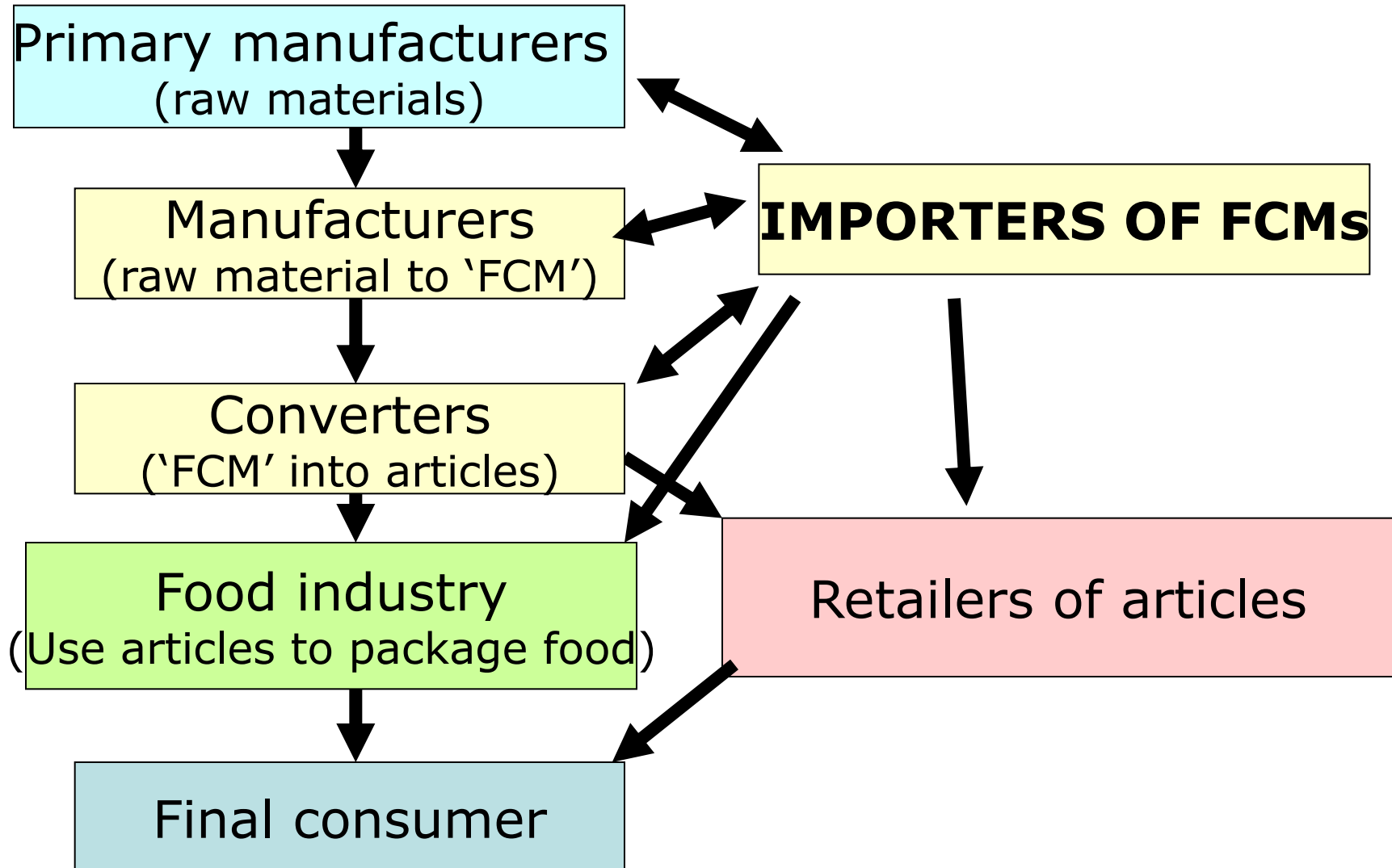
(To be signed by the Manufacturer, the Consignee or the Consignor)

Signed [Signature] Print Name [Name]

Company Name, Address and Contact E mail and Telephone No. [Address]



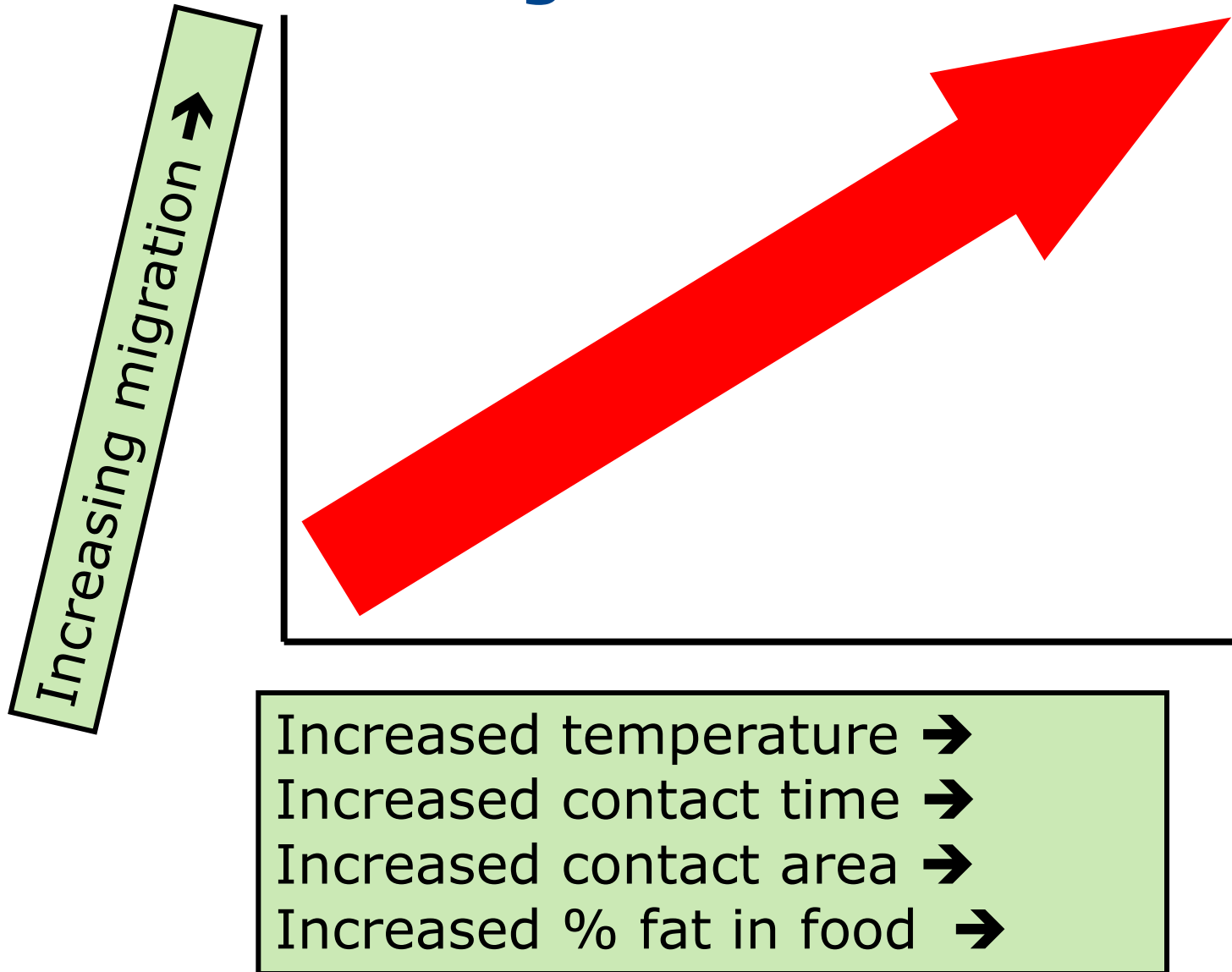
# FCM supply chain



# **ASSUMPTION 2: EXPERTISE**



# Effects on migration



## Migration tests are done, using model 'foods' for 5 food types

<u>Food type</u>	<u>Food simulant</u>
Aqueous foods:	10% ethanol/water
Acidic foods:	3% acetic acid/water
Alcoholic foods:	20% ethanol/water
Fatty foods:	Vegetable oil or 50% ethanol
Dry foods:	Tenax <sup>®</sup> polymer

Temperature, surface area & contact time also affect migration

*So packaging may be suitable for some applications and not others:*

***Does **actual** use match the **intended** use?***



# **FSAI SUPPORTS**



# Supports for ...

Our Inspectors

Manufacturers of FCM

Importers/Distributors of FCM

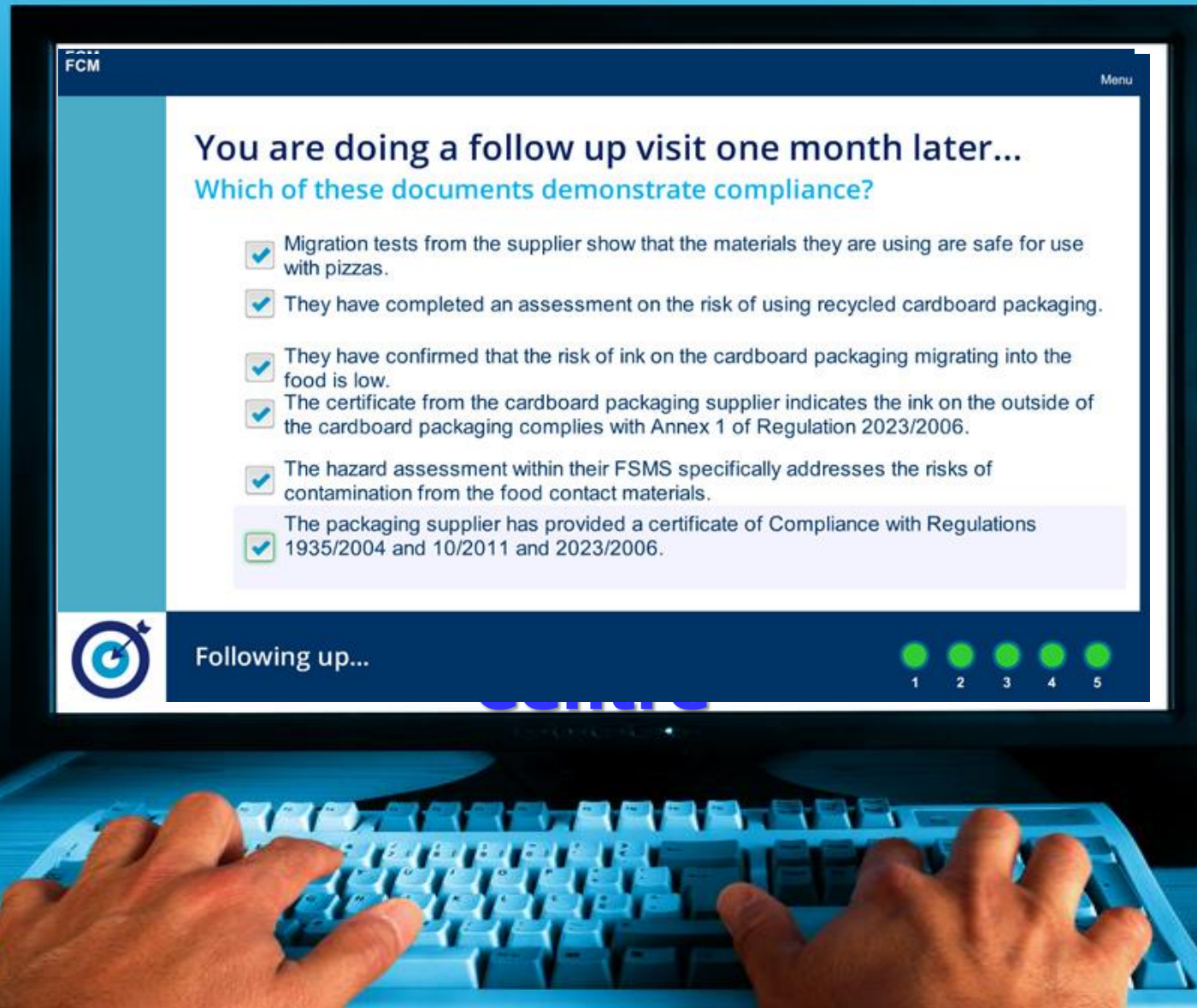
Food Businesses using FCM

Available on [www.fsai.ie](http://www.fsai.ie) (search  
'Food contact materials')





# A Range of Educational Tools...



# Interactive Video Tutorials

Available on [www.fsai.ie](http://www.fsai.ie) (search  
‘Food contact materials’)

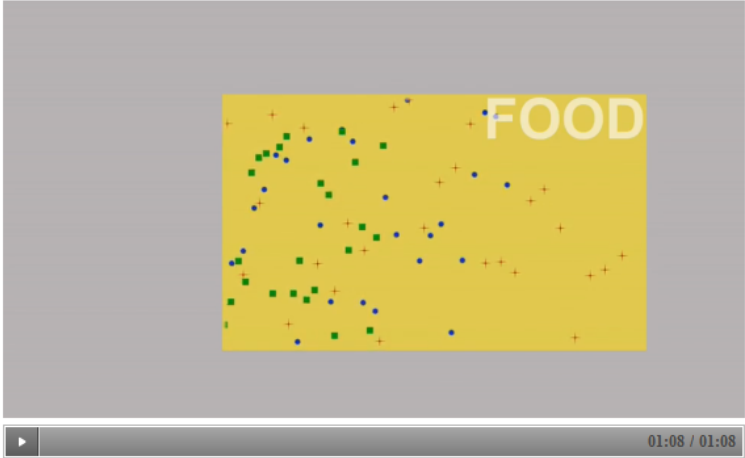


# Simple animations


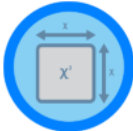

Introduction to Food Contact Materials

RESOURCES MENU

Play the short video for more information on the factors affecting the migration of FCMs.

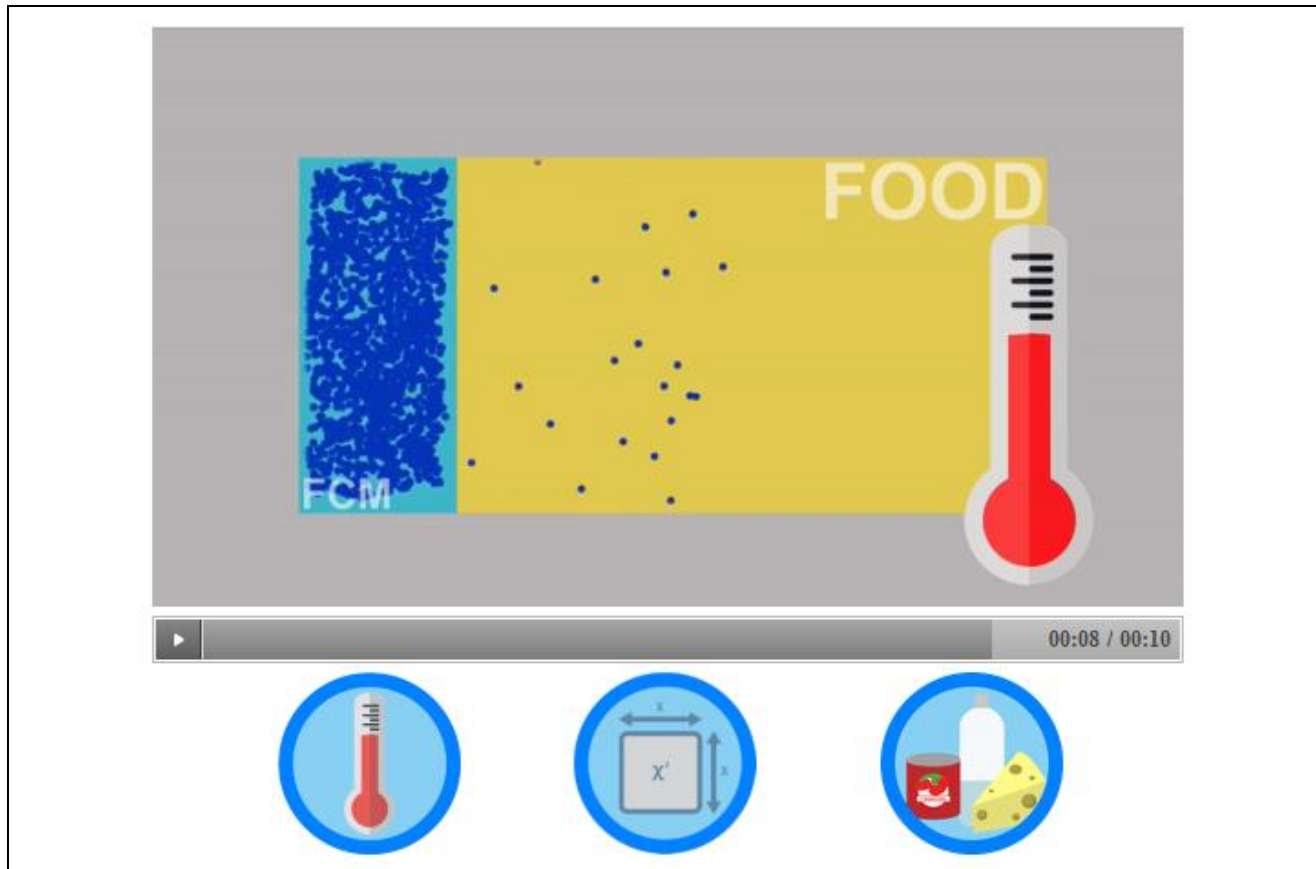


01:08 / 01:08

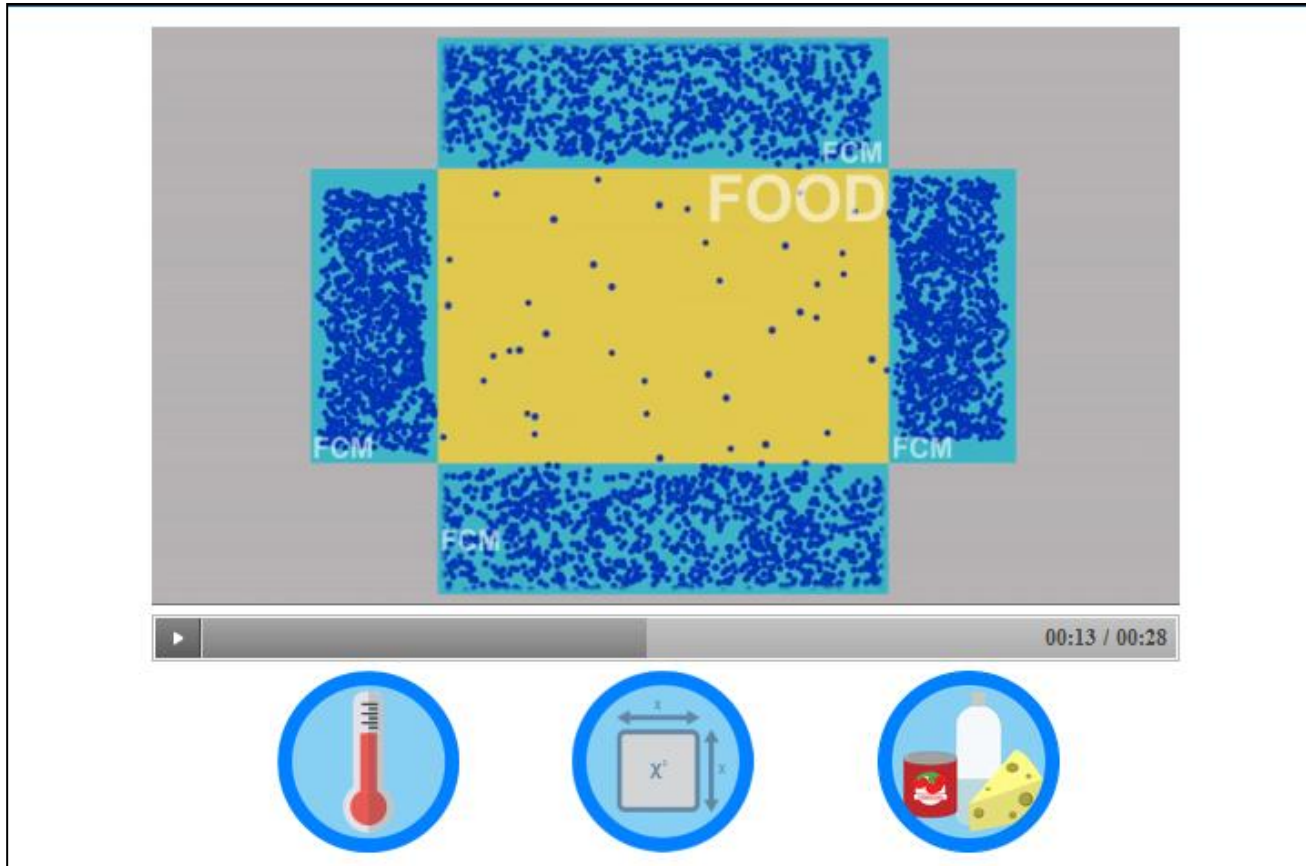


Food Contact Materials and the Risk of Migration

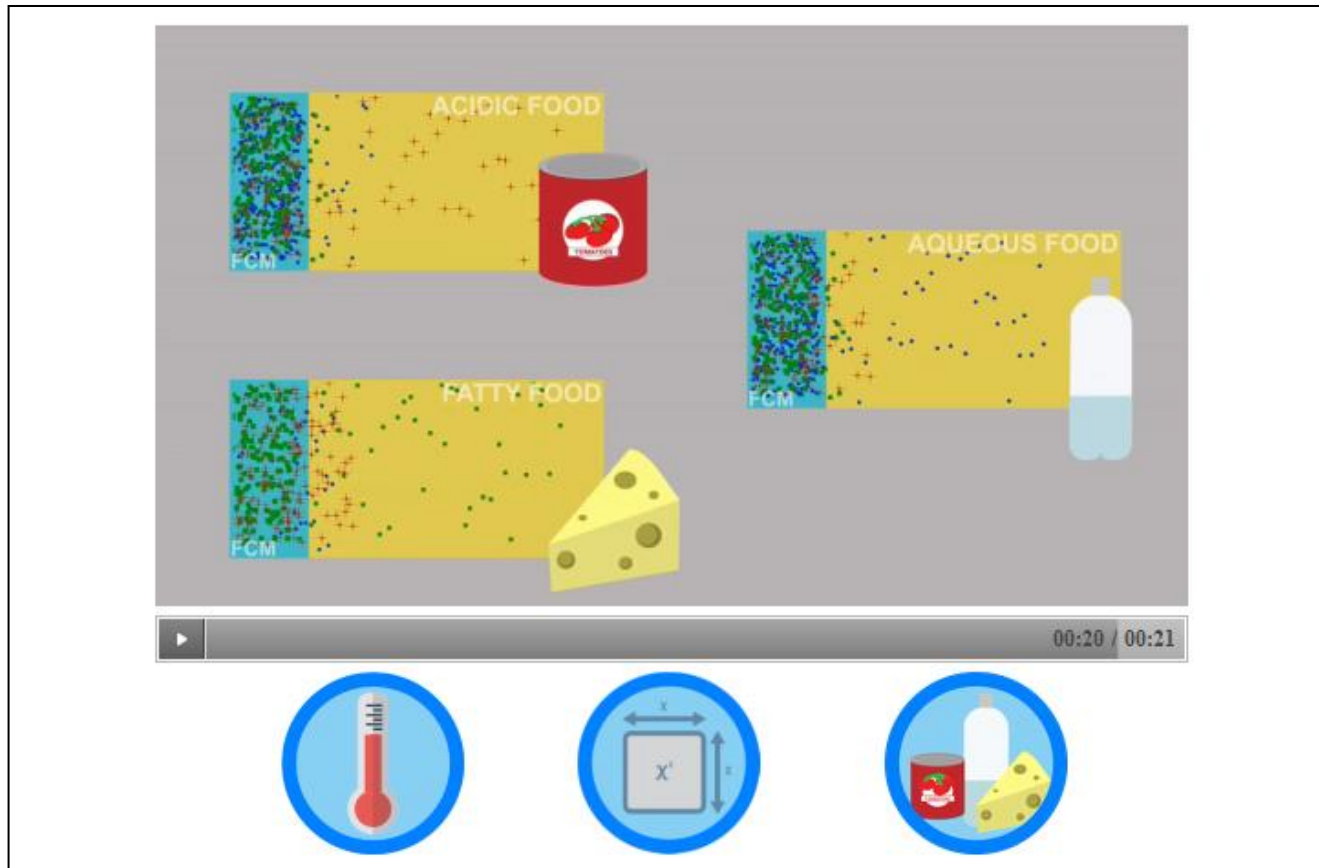
# Effects of temperature



# Importance of S/V ratios



# Effect of food types on migration



# How do food business know how to use the FCM safely?



**...it must be declared in writing!**





# Helping to produce a better Declaration of Compliance for plastics

## It's as easy as 1, 2, 3

A supplier needs to supply a written Declaration of Compliance (DoC) document for plastics materials and final articles, including substances and intermediate products that are intended to come into contact with food.

OLLIE (On Line Learning Information Expert) is the brains behind Easy DoC and will guide you through 3 simple steps to create a checklist that you can use to help understand what is required in the Declaration of Compliance for your product.

**Click on the questions that have been posed to OLLIE in the past about Easy DoC.**



### Using Easy DoC



1. Define your product
2. Refine your investigation
3. Name your checklist

**GET STARTED** ►

**GET STARTED** ►

**<http://easydoc.fsai.ie/> makes a checklist**





# Declaration for plastics: Reg. 10/2011

1. Name & address of the business issuing declaration
2. Name and address of EU manufacturer or importer of food contact material, or FCM substances
3. Identity of the plastic material or substances
4. Date of declaration
5. Confirm that FCM complies with Reg 10/2011 & Reg 1935/2004
6. Information on any substances used for which there are restrictions under Reg 10/2011 to allow users to comply
7. Information on any substances used for which there are restrictions under food law, to allow users to comply
8. Specifications for safe use (foods, time/temp, S/V)
9. For plastic multi-layer materials using 'functional barrier' layers, confirmation that finished FCM complies with relevant parts of Reg 10/2011

1

## DECLARATION OF COMPLIANCE

Manufacturer

**Hegarty S.A.**

Av. De las Violetas, s/n  
Poligono Industrial Monfort,  
Sevilla, SPAIN

Product covered by this declaration

PET Box SN.4563

Date of the declaration

25.09.2014

Declaration of compliance with

- This product complies with Regulation (EC) No. 10/2011 (as amended).
- This product complies with Regulation (EC) No. 1935/2004 (as amended).
- This product complies with Regulation (EC) No. 2023/2006 (as amended).

This plastic box has been manufactured only with monomers, other starting substances and additives that are authorised under Regulation (EC) No. 10/2011.  
A risk assessment according to Article 19 of Regulation (EC) No. 10/2011 was performed for this product.

Information about the compliance of substances used that are subject to any restriction or specification

Compliance with overall migration limit

Overall migration is below 10mg/dm<sup>2</sup> under standard testing conditions laid down in Regulation (EC) No. 10/2011. Additional information can be provided on request.

Individual substances

Specific Migration Limits (SMLs)

Test results (or estimated level of migration from calculations)

1. 1-hexene

3 mg/kg

SMLs cannot be exceeded for s/v

2. Isophthalic acid

5 mg/kg

contact ratio below 6 dm<sup>2</sup>/kg.

Information about the compliance of substances subject to purity criteria.

There are no substances subject to purity criteria.

There are no substances subject to restrictions apart from the Specific Migration Limits (SMLs).

Information about the use of "dual-use" additives in the material.

No dual use additives were used in the manufacture of this product.

Conditions of use

- Type(s) of food with which it is intended to be put in contact  
All foods.
- Time and temperature and storage while in contact with the food  
Cold storage for up to 10 days.
- The ratio of food contact surface area to volume used to establish the compliance of the material or article

The compliance testing was done under conditions set out in Regulation (EC) No. 10/2011 using a surface to volume [s/v] contact ratio of 6 dm<sup>2</sup>/kg.

Functional Barrier

There is no functional barrier present.

2

4

5

6

7

8

9

# Sample of a Declaration of Compliance for plastics



# CAPERPLEX IMPORTS CO.

45 – 47 Imaginary St., Malahide,  
Co. Dublin, Ireland  
Phone: 00-353 11 1111 111  
Fax: 00-353 11 1111 112  
E-mail: [clients@caperplex.ie](mailto:clients@caperplex.ie)  
Webpage: [www.caperplex.ie](http://www.caperplex.ie)

1

## DECLARATION OF COMPLIANCE

Manufacturer

**Hegarty S.A.**

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Date of the declaration

25.09.2014

4

Declaration of compliance with

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5

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Overall migration is below 10mg/dm<sup>2</sup> under standard testing conditions laid down in Regulation (EC) No. 10/2011. Additional information can be provided on request.

### Individual substances

### Specific Migration Limits (SMLs)

### Test results (or estimated level of migration from calculations)

1. 1-hexene
2. Isophthalic acid

3 mg/kg  
5 mg/kg

SMLs cannot be exceeded for s/v contact ratio below 6 dm<sup>2</sup>/kg.

## Information about the compliance of substances subject to purity criteria.

There are no substances subject to purity criteria.

There are no substances subject to restrictions apart from the Specific Migration Limits (SMLs).

## Information about the use of "dual-use" additives in the material.

No dual use additives were used in the manufacture of this product.

## Conditions of use

- **Type(s) of food with which it is intended to be put in contact**  
All foods.
- **Time and temperature and storage while in contact with the food**  
Cold storage for up to 10 days.
- **The ratio of food contact surface area to volume used to establish the compliance of the material or article**

The compliance testing was done under conditions set out in Regulation (EC) No. 10/2011 using a surface to volume (s/v) contact ratio of 6 dm<sup>2</sup>/kg.

## Functional Barrier

There is no functional barrier present.

6

7

8

9



# Note to plastics suppliers



## NOTE ON THE END OF THE 3-YEAR TRANSITION PERIOD OF REGULATION (EC) NO.10/2011

Regulation (EC) No 10/2011 on plastic materials and articles intended to come into contact with food came into effect in May 2011. It replaced the older Directive 2002/72/EC on plastics. The Regulation applies to plastic food packaging and other plastic food contact materials. For some of the changes introduced in the Regulation for plastics, the Commission included a three-year transition period so as to reduce the burden on industry and ensure a gradual move to the new rules. **This transition period ends on 31 December 2015.**

### WHAT IS CHANGING?

With effect from 1 January 2016, there is a change to how plastics intended for use in contact with food must be tested. There are tests carried out on all plastics to confirm that migration of substances is within the specified or overall migration limits (SMLs or OML). These migration tests must be done in future under the test conditions specified in Annex V and using the test simulants in Annex III to Regulation (EC) No 10/2011.

This applies to all plastics food contact materials such as plastic film, trays and bottles. The previous Directive 2002/72/EC on plastics specified that the migration tests were done in line with Council Directive 82/711/EEC, using test simulants specified in Council Directive 85/572/EEC. (Test simulants are simple materials, usually liquids, used in migration tests to represent different types of foods.) The old test simulants were:

Food Simulant, Directive 85/572/EEC	Abbreviation	Used for
Distilled water	Food Simulant A	Aqueous foods
	Food Simulant B	Acidic foods



# Summary

Producing safe FCM is an industry responsibility

Food packaging and food industries need to co-operate to ensure safe food, compliant with regulations

Official controls to ensure it is safe are the responsibility of Member States

Official controls check compliance with:

- Regulation (EC) No 1935/2004
- Rules on GMP
- Specific and individual substances rules

Supports are available



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