

THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)

Joint EDQM-AESAN symposium on “Recent developments in food contact materials and articles”

Majadahonda Campus, 18 September 2024



Official control and enforcement

The true reality of official control: Observations from border and manufacturing site inspections

Cátia Simões (DGAV)

1. Organisation of the Portuguese Food Safety Services

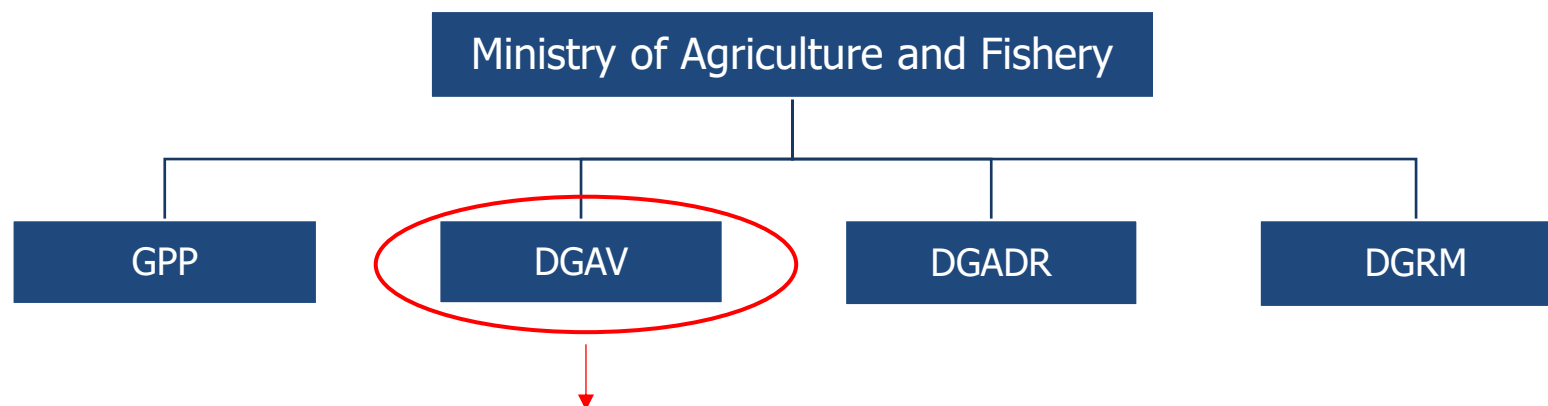
2. Official Controls of Food Contact Materials

2.1 Control Plan of Food Business Operators (FBOs)

2.2 Control Plan of FCM

2.3 Import Control Plan

1. Organisation of the Portuguese Food Safety Services



DGAV - General Directorate of Food and Veterinary

MISSION

Definition, coordination of the implementation and and assessment of policies of:

Food Safety

Animal health and welfare

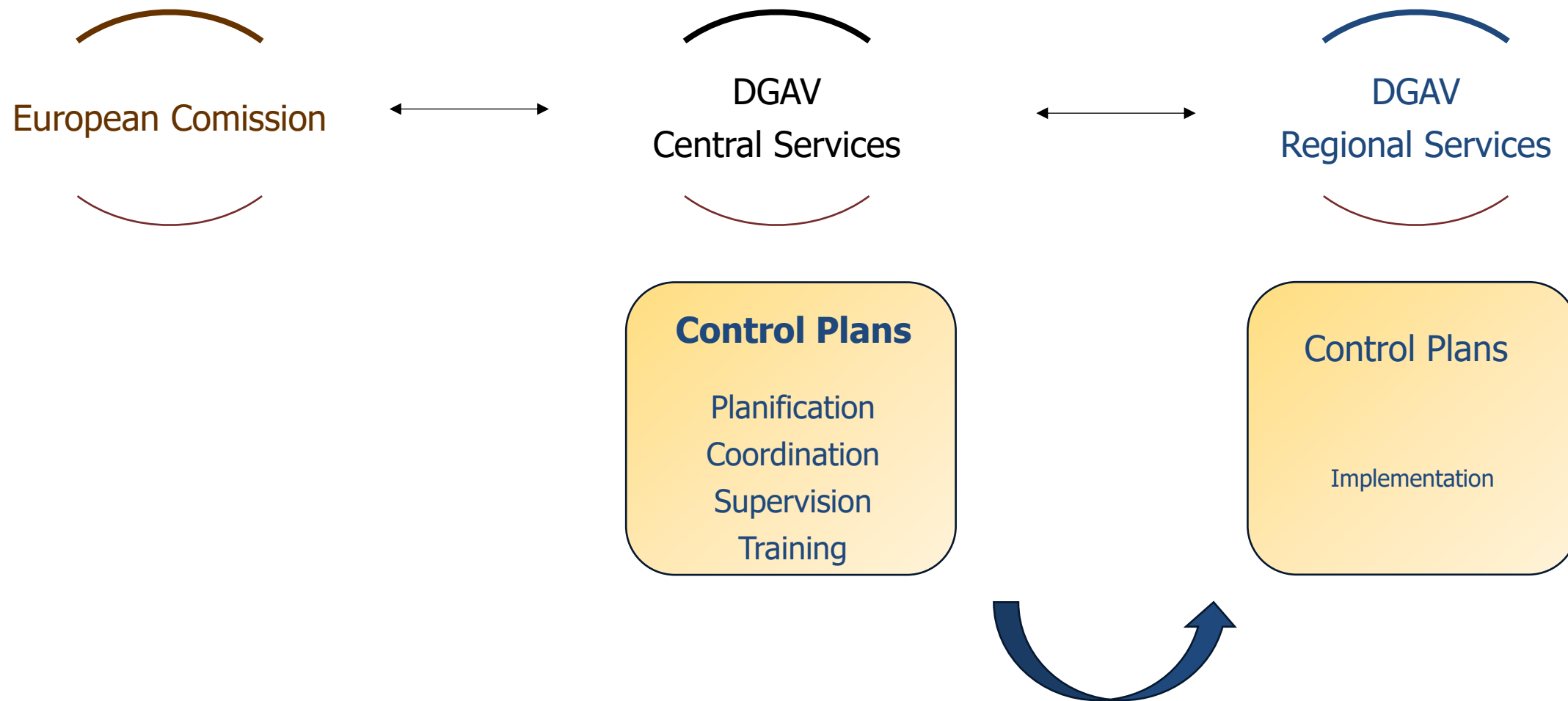
Plant protection and plant health

1. Organisation of the Portuguese Food Safety Services

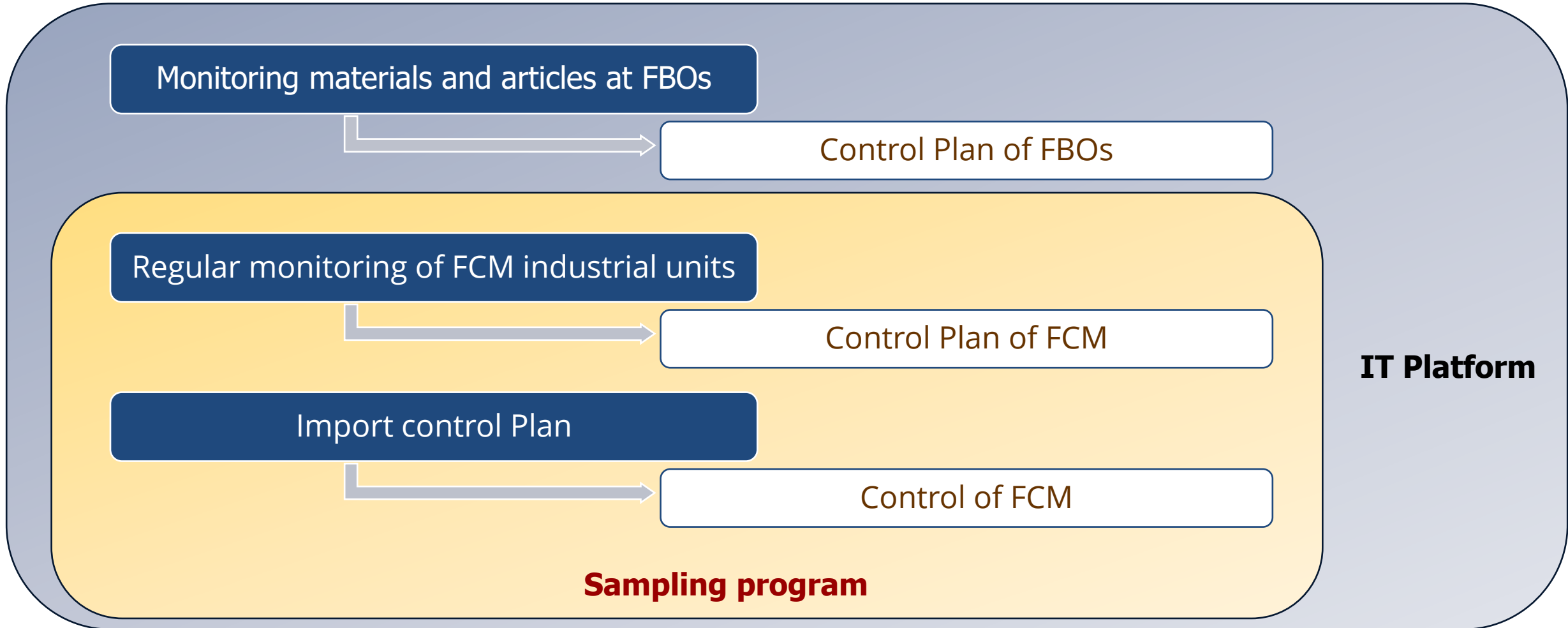
Location of DGAV Services



1. Organisation of the Portuguese Food Safety Services



2. Official Controls of Food Contact Materials



2. Official Controls of Food Contact Materials

2.1 Control Plan of FBOs

Equipment/Utensils that come into contact with food



Packaging of food



2. Official Controls of Food Contact Materials

2.1 Control Plan of FBOs

Main problems in equipment/Utensils that come into contact with food

Reuse of packaging



Incomplete or misinterpreted Declaration of Compliance (DoC)



Equipment/Utensils operation conditions



2. Official Controls of Food Contact Materials

2.1 Control Plan of FBOs

Main problems in Packaging of food

DoC incomplete or misinterpreted



2. Official Controls of Food Contact Materials

2.2 Control Plan of FCM

Different types of control in place

Regular

- time intervals set according to risk criteria
- organized by category and by type of establishment

Verification

- verify if non-compliances detected at previous control, was corrected

Suspicion

- as a result of becoming aware of increased risk in a given establishment

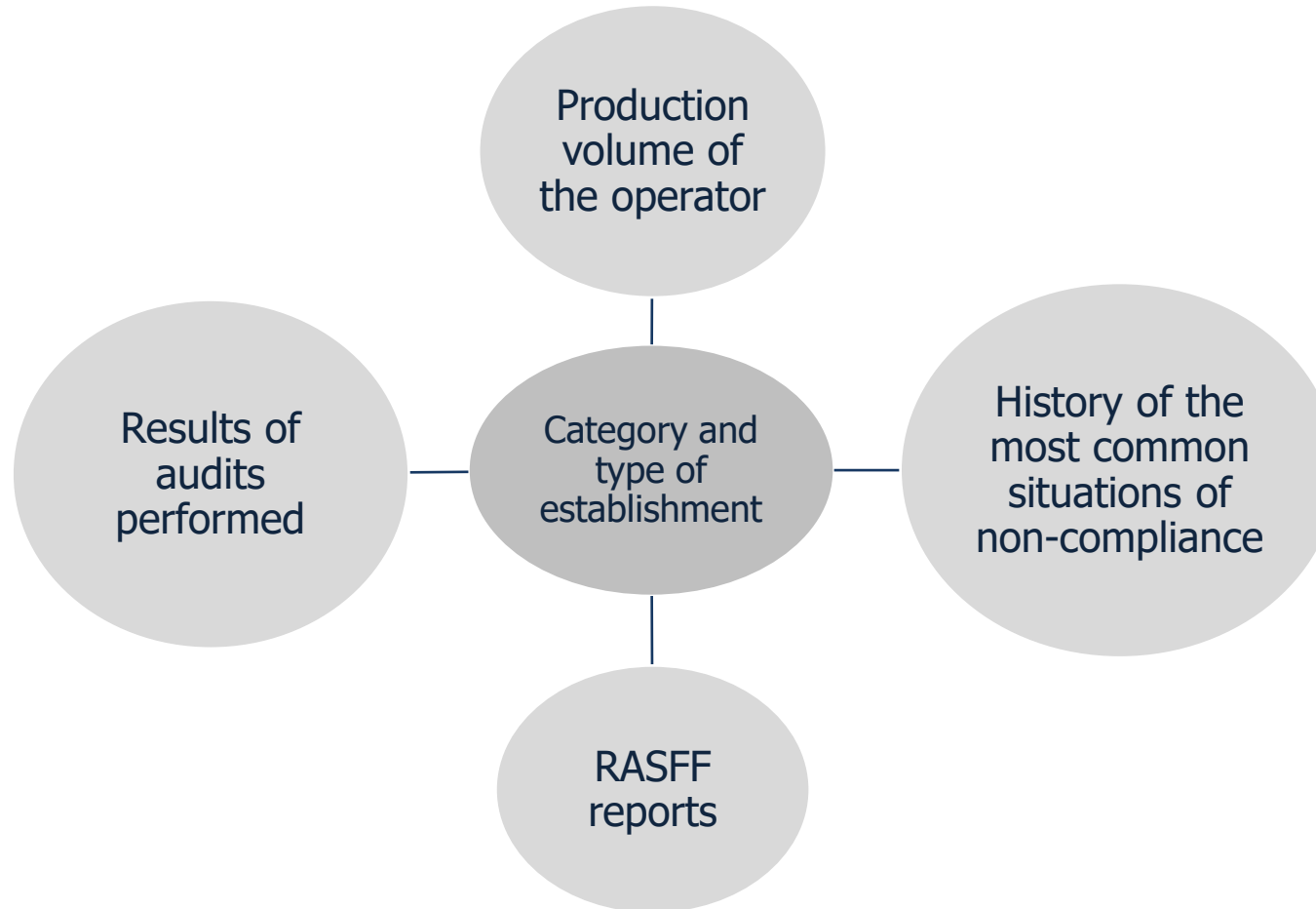
Specific

- reasons other than the mentioned above

2. Official Controls of Food Contact Materials

2.2 Control Plan of FCM

Frequency of controls – is based on a risk analysis



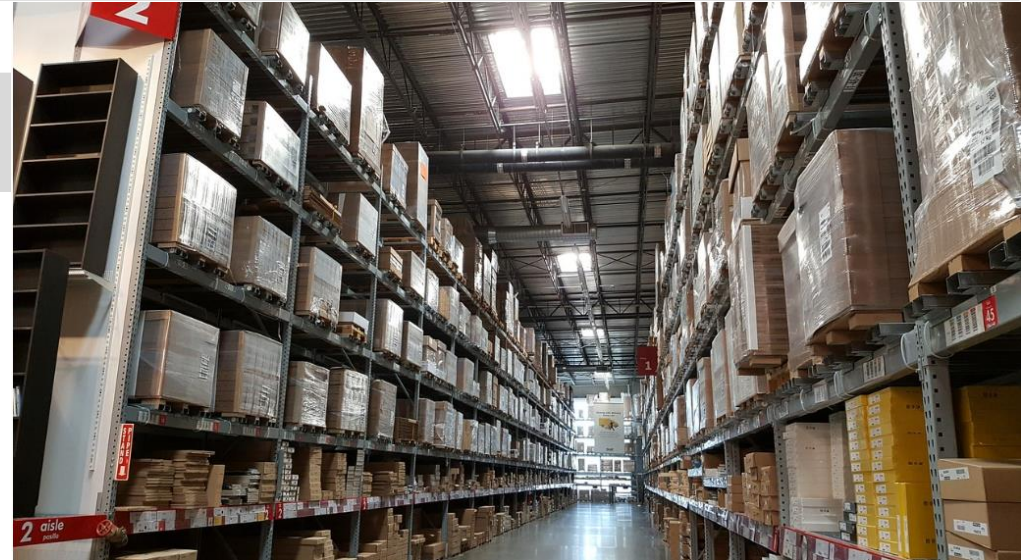
2. Official Controls of Food Contact Materials

2.2 Control Plan of FCM

FCM in the warehouse

Verification of DoC and supporting documentation concerning material and articles

Sampling



2. Official Controls of Food Contact Materials

2.2 Control Plan of FCM

FCM Manufacturing

Traceability

Verification of the requirements related to traceability

DoC

Verification of the DoC concerning materials produced in the establishment

Compliance

Verification of the compliance documentation (DoC starting materials, NIAS analysis, organoleptic tests...)

GMP

Checking if manufacturing operations are carried out in accordance with Good Manufacturing Practices (GMP)

Inks

Checking information manufacturing practice about printing inks

Labelling

Verification of FCM labelling

2. Official Controls of Food Contact Materials

2.2 Control Plan of FCM

FCM Manufacturing

Informação sobre o Relatório de Controlo Oficial			
O resultado da verificação de cada item é assinalado do seguinte modo:		Abreviaturas usadas nas referências à legislação:	
C/NC/NA/NV		alíq.	Alínea
C	Cumprimento da norma	art.	Artigo
NC	Não cumprimento da norma	Cap.	Capítulo
NA	Norma não aplicável	Port.	Portaria
NV	Norma não verificada	Reg.	Regulamento
Os factos que constituem incumprimentos são descritos no relatório de controlo, sendo efetuado a referência à norma legal contrariada.			
Resultado do Controlo Oficial- Materiais Plásticos			
A. Rastreabilidade			
		C/NC/NA/NV	Facto
A.1	Matérias-primas		
A.2	Produto final		
A.3	Rotulagem		
A.4	Retirada do mercado		
Comentários:			
B. Declaração de Conformidade			
		C/NC/NA/NV	Facto
Identificação			
E.1	Declaração inicial		
E.2	Identificação do Transformador		
E.3	Identificação do plástico reciclado		
E.4	Identificação da autoridade competente		
Conformidade			
		C/NC/NA/NV	Facto
E.14	Identifica o maior rácio entre a área superficial em contacto e o volume		
E.15	Identifica as substâncias adicionadas com limites de migração		
E.16	Fornecer informação sobre aditivos ou substâncias iniciadoras		
E.17	Outra Declaração no caso de materiais multicamadas		

Traceability

DoC

C. Conformidade			
		C/NC/NA/NV	Facto
Requisitos aplicáveis à recolha e ao pré-tratamento			
B.1	Proveniencia dos resíduos		
B.2	Recolha seletiva		
B.3	Composição dos resíduos		
B.4	Controlo dos resíduos		
Requisitos de descontaminação			
		C/NC/NA/NV	Facto
C.1	Qualidade materiais plásticos de partida		
C.2	Critérios do processo de descontaminação		
C.3	Equipamento de descontaminação		
F. Boas Práticas de fabrico			
		C/NC/NA/NV	Facto
F.1	Sistema de garantia da qualidade		
F.2	Número de efetivos		
F.3	Dimensão da empresa		
F.4	Requisitos de substâncias iniciadoras		
F.5	Procedimentos- fluxograma		
F.6	Medidas corretivas		
F.7	Documentação		

Compliance

GMP

G. Impressão			
		C/NC/NA/NV	Facto
G.1	Utilização de tintas		
G.2	Informação sobre as tintas		
G.3	Manuseamento dos materiais impressos		
H. Rotulagem dos produtos			
		C/NC/NA/NV	Facto
H.1	Contacto alimentar		
H.2	Instruções especiais		
H.3	Identificação		
H.4	Rastreabilidade		

Inks

Labelling

2. Official Controls of Food Contact Materials

2.2 Control Plan of FCM

FCM Manufacturing

When it does not comply, there is a rating:

PCMC	1	2	3	4
Indicators	Absence	Smaller	Bigger	Critical
		Any non-compliance not mentioned in the following degrees where the conditions, requirements and principles of the Regulations are not respected.	Any non-compliance that potentially endangers public health.	Any non-compliance that puts public health at immediate risk

A. TRACEABILITY

	GC	2	3	4
Raw materials	1,2,3,4 Possible to identify the supplier of all raw materials.	Incipient traceability	Just a few	No
End product	1,2,3,4 It is possible to identify to whom the materials or objects produced were supplied.	Incipient traceability	Not always	No

2. Official Controls of Food Contact Materials

2.2 Control Plan of FCM

FCM Manufacturing - RESULTS

2022 - Conformity degrees

Manufacturing	Metals			Plastics						Ceramics						Paper			
Trace	3	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1
DoC	3	1	2	2	1	1	2	3	1	0	0	0	4	1	1	0	0	1	0
Accord	0	1	0	1	1	1	2	2	0	3	1	1	0	1	1	2	1	0	2
GMP	2	2	3	1	1	1	2	2	0	2	1	1	3	1	2	2	1	1	2
Printing	0	0	0	1	1	0	0	1	0	0	0	0	0	0	1	0	0	0	0
Labeling	2	1	2	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1

2023 - Conformity degrees

Manufacturing	Metals			Plastics						Ceramics						Paper			
Trace	1	1	1	1	1	1	1	1	1	1	1	3	3	3	0	1	1	1	1
DoC	2	3	1	1	2	1	2	2	2	2	1	2	2	3	0	0	1	1	1
Accord	0	0	1	2	1	1	2	2	3	1	1	2	2	3	1	1	1	0	0
GMP	3	2	1	1	1	1	1	1	1	1	1	3	3	3	1	1	1	1	1
Printing	0	0	1	0	0	0	1	1	0	0	1	0	0	0	0	0	1	0	0
Labeling	1	2	1	1	1	1	1	1	1	1	1	2	2	2	0	1	1	1	1

2. Official Controls of Food Contact Materials

2.2 Control Plan of FCM

FCM Manufacturing

Conclusions

There are more non-compliances in the FCM on which we have now started to make controls.

It is more difficult to implement the regulation in the manufacture of materials where we have longer traditions. It may not be clear whether it is a FCM or a decoration.



2. Official Controls of Food Contact Materials

2.3 Import Control Plan

Frequency of the different controls

100%

Document checks

5%

Identity and physical control (without sample collection)

10%

Analytical control (polyamide and melamine Reg. 284/2011)



2. Official Controls of Food Contact Materials

2.3 Import Control Plan

FCM of	
Plastics	Taric code 39
Ceramics	Taric code 69
Metals and alloys	Taric codes 73+82+76
Others	Errors

- 73- Articles of iron or steel 73
- 82- Tools, implements, cutlery, spoons and forks, of base metal
- 76- Aluminium and articles thereof
- Glass, paper, wood... there is no provision for import control



Subject to import control

2. Official Controls of Food Contact Materials

2.3 Import Control Plan

RESULTS

	N° of consignments		N° of rejected consignments	
	2022	2023	2022	2023
Plastics	556	672	17	11
Ceramics	354	460	1	1
Metals and alloys	692	658	2	13
Others	241	260	1	5

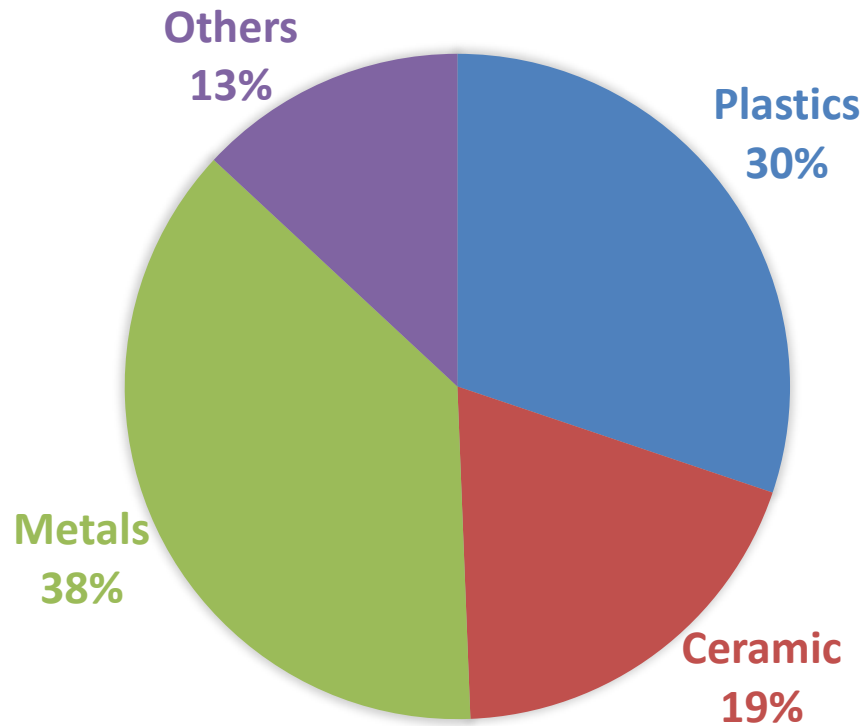
TRACES databases

2. Official Controls of Food Contact Materials

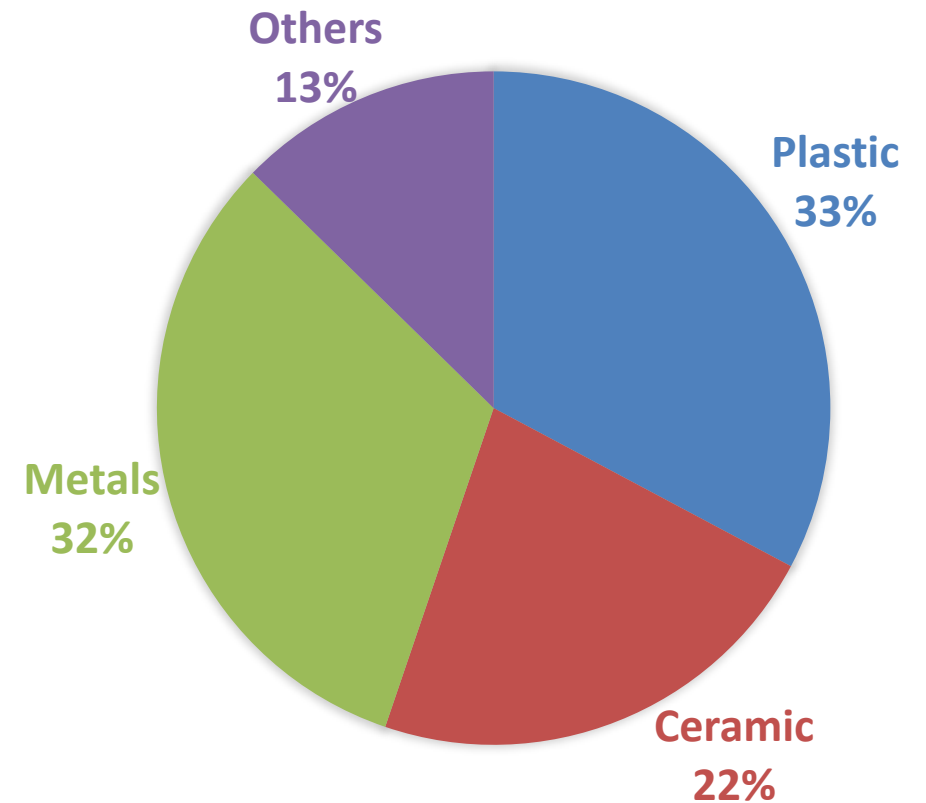
2.3 Import Control Plan

RESULTS

% of consignments /FCM 2022



% of consignments /FCM 2023

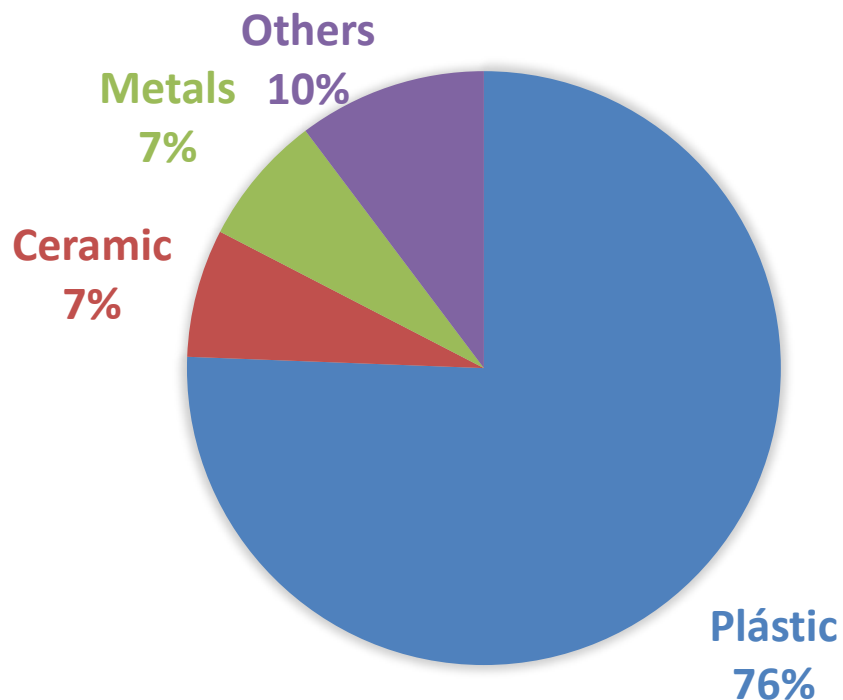


2. Official Controls of Food Contact Materials

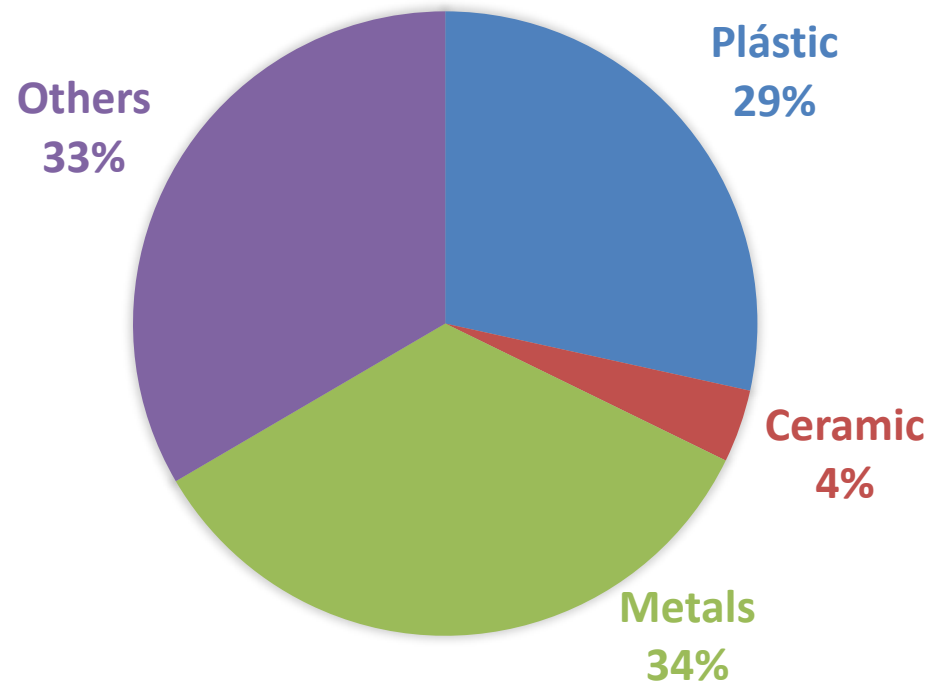
2.3 Import Control Plan

RESULTS

% of consignments rejected/FCM 2022



% of consignments rejected/FCM 2023



2.Official Controls of Food Contact Materials

2.3 Import Control Plan

Conclusions

The number of consignments /FCM type is similar in 2022 and 2023

There is an increasing number of rejected consignments /by fcm type in metals and others



Thank you for your attention



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