

Annex 3 PROGRAMME ON FOOD CONTACT MATERIALS

DAY 1: Welcoming address and introduction on food Contact Material and the EU legal framework

Before 13:30 // Arrival and registration of participants

13:30 – 14:00

Welcome address



GEM01

Training objective / subjects covered

Delivery of the training material (folder and memory stick).

To introduce the BTSF course “Food Contact Material” Welcome address, presentation of the program and the objectives, introduction of tutors, participants and participants’ expectations

BTSF promotional movie

Method of training:

Lecture Day 1.1

Questions and Answers

Media: BTSF video

Responsible tutor

Event Manager and Training Coordinator

Zoe Mousia

Bernard Hegarty or Katri Kempfi

Koni Grob or Jose-Angel Garde Belz

14:00 – 14:20

Pre-Course Test



GEM02

The OMBEA tool is used to assess and collate answers to the opening questionnaire

- 15 questions asked with OMBEA tools
- General knowledge on food Contact Material, Legislation and official Control

Method of training:

Pre-Test

Questions

Responsible tutor

Training Coordinator

Zoe Mousia

14:20 – 15:20

Module 1: Lecture on legal provisions on FCM



LPM01

Training objective / subjects covered

The objectives are:

- To know the strategic approach of the EU to the FCM control and harmonization process of FCM legislation;
- To know the **specific legislation** of some FCM in the European Union and reference to the non-harmonized (e.g.: JRC report)
- To know the **specific legislation** and most recent legislation adopted in the EU level on FCMs;
- To know how FCM safety and compliance is established and why BO are responsible for ensuring compliance of their FCMs
- To know practical information in the FCM control and information on techniques

Content:

- The general and specific requirements for compliance of FCM with of Regulations (EC) No 1935/2004 and the specific measures apply to each material
- The role of EFSA, Commission and National Competent Authorities
- EU guidelines on plastic materials (Regulation (EU) No 10/2011) and on information in the plastics supply chain

Method of training

Lecture Day 1.2

Questions & answers

Responsible tutor

Training Coordinator & Tutor

Zoe Mousia**Bernard Hegarty or Katri Kempf****15:20 – 15:50****Icebreaking Coffee Break**

GEM03

Training objective / subjects covered

Each participant receives half of a material or articles. He/she has to find the participant with the 2nd half of the same picture and to learn about who she/he is and what her/his professional background is.

Zoe Mousia**Bernard Hegarty or Katri Kempf****Koni Grob or Jose-Angel Garde Belz****15:50– 16:20****Round-table of trainees**

GEM04

Each participant introduces his/her partner from the icebreaking coffee break :

- Name, Country
- Position, main activities, National or Regional Level, Background.

Zoe Mousia**Bernard Hegarty or Katri Kempf****Koni Grob or Jose-Angel Garde Belz****16:20-16:50****Module 3: Enforcement of GMP Regulation**

GMP01

Training objective / subjects covered

The objective is to introduce the regulation on the application of GMP and the requirements.

To discuss the harmonized implementation of the official controls (the new regulation) in the enforcement of GMP Regulation in combination with tools such as Industry's Guides on GMPs for FCMs, EU and national guidelines for the official control, checklists) and national measures for sanctions for non-compliances.

Method of training

Lecture 1.3

Questions and Answers

Responsible tutor

Training Coordinator & Tutor

Zoe Mousia**Bernard Hegarty or Katri Kempf****16:50– 17:20**

Module 1: Lecture on risk assessment of FCM



Training objective / subjects covered

The objective is to introduce the guidelines with the tiered approach in the assessment of FCM substances contained in FCM and potentially migrating from them (not only starting substances and additives but also oligomers, NIAS) Lecture also will deal with data requirement, from FBOs when they make risk assessment for their FCM materials and products.

Method of training

Lecture Day 1.4
Questions & answers

Responsible tutor

Training Coordinator & Tutor
Zoe Mousia
Koni Grob or Jose-Angel Garde Belz

17:20 – 17:50

Module 1: Quiz on the different material used and articles



Training objective / subjects covered

Short Quiz on the specific requirement of different FCM materials and control of their compliance in the supply chain with the reference to the EU guidelines, and the material that are regulated only at international level (where mutual recognition applies)

Method of training

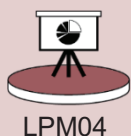
Quiz Exercise
Questions &
answers

Responsible tutor

Training Coordinator & Tutor
Zoe Mousia
Koni Grob or Jose-Angel Garde Belz

17:50 – 18:20

Module 1: Requirement of materials



Training objective / subjects covered

Information on how to control the FCM compliance in respect of documentation, and assessment of Supporting Documentation such as information on composition (i.e. substances with restrictions, NIAS) received DoCs from intermediate products, results from migration tests (overall and specific migration), industry's risk assessment, etc).

General requirement such as traceability, application of GMPs during production or conversion

Method of training

Lecture Day 1.4
Questions & answers

Responsible tutor

Training Coordinator & Tutor
Koni Grob or Jose-Angel Garde Belz
Bernard Hegarty or Katri Kempfi
Zoe Mousia

19:00 // Welcome drink

19:30 // Dinner at the hotel

DAY 2: Official Control of FCM

08:20 – 09:00

Module 2: Practical group Exercise: Preparation of visit and checklist



OCP01

Training objective / subjects covered

The objective is to prepare participants to the visit of a packaging industry
Preparation for audit activities (desk review, risk-based targeting, check-list development
Preparation by competent authorities of checklists for inspectors: 3 groups working on how to build a checklist on the control of FCM compliance related to the stage of the supply chain (FCM producing plant) in terms of Traceability, implementation of GMP, DoCs, Supporting Documentation etc. The duration of checklists' preparation will 20 minutes and 5 minutes for their presentation to the audience (flipchart).

Method of training

Quiz Exercise

Responsible tutor

Training Coordinator & Tutor

Zoe Mousia

Jan Arnaut

Bernard Hegarty or Katrin Kempf

Koni Grob or Jose-Angel Garde Belz

9:00-12:30

Module 2: Visit of FCM industry



OCP02

Training objective / subjects covered

The main objective of the visit is practical experience of FCM production and control by visiting an FCM producer/convertor.

The specific objective is to discuss the application by the industry of FCM requirements during their production to ensure their safety and compliance as laid down in the FCM legislation Reg. (EC) No 1935/2004 and Regulation (EC) No 2023/2006 and the specific measures apply to them.

Moreover, to discuss the implementation of official control and audit by competent authorities (Regulation (EU) No 882/2004 and new regulation 2017/625) that is to know how to control FCM compliance in FCM production industry, using tools such GMP guides, EU and national guidelines, checklists etc.

The visit will be divided into 5 parts:

Introduction of the food contact material industry; introduction of the QMS, certificates and control plan, documentation by the Operators (e.g. certificates, composition, migration tests etc.)

Working group: The audience will be divided into 3 groups in order each group will visit the FCM industry on the basis of the checklist created the day before, on requirements for GMP, traceability, and DoC/supporting Documentation in FCM premises. Each group will fill in form the checklist during the visit.

Visit: Practical training on how to inspect application of GMPs, declaration of compliances and supporting documentation

Restitution on the audience: presentation of the 3 checklists in front of the audience

Discussion in plenary: On the basis of the observations made during the morning, discussions and questions on the harmonisation of GMP practices (or other topic such as DOC & Supporting Documentation and in-house-control) and inspection in EU Member states

Synthesis of observations by small groups of trainees.

- Observation of Construction, Layout, Processes, Materials, Equipment
- Observation of Good Manufacturing Practices, and Documentation
- Observation of practices of (in-house control, Declaration of Compliance, Supporting Documentation)
- Observation of traceability and Labelling

Method of training

Responsible tutor

Visit of packaging industry
Discussion with the FCM
Businesses Operator
representative at the company

Training Coordinator & Tutor
Zoe Mousia
Jan Arnaut
Bernard Hegarty or Katrin Kempf
Koni Grob or Jose-Angel Garde Belz

12:30 – 13:30 // Lunch break

13:30 -14:00

Module 2: Discussion of official control in FCM industry



OCP03

Training objective / subjects covered

Observation, discussion and recording of comments on the application of Reg. (EC) No 1935/2004 and Regulation (EC) No 2023/2006 and the specific measures apply to them. Result of the discussion will enable inspectors to make corrections on the checklist based on the experience during the field visit and to understand the importance of use of checklists during inspections.

Method of training

Discussion

Responsible tutor

Training Coordinator & Tutor
Zoe Mousia
Jan Arnaut
Bernard Hegarty or Katrin Kempf
Koni Grob or Jose-Angel Garde Belz

14:00 -14:45

Module 2: Control of FCM articles (e.g. : kitchen wares from Third Countries)



OCP04

Training objective / subjects covered

The objective of the lecture is to deal with general and specific requirements of FCM articles such as kitchenware. . Information to the consumers, issues of compliance and focus on proper labelling will be discussed.

Method of training

lecture

Responsible tutor

Training Coordinator & Tutor
Zoe Mousia
Milada Sycova
Jan Arnaut
Bernard Hegarty or Katrin Kempf
Koni Grob or Jose-Angel Garde Belz

14:45 – 15:00

Module 2: Control of FCM plastic recycling plant



OCP05

Training objective / subjects covered

The objective is to explain to the participants of the issues in the control of recycling plants with focus to the differences from the control of the conventional plants that will be dealt in depth in a different training course.

Method of training

Quiz Exercise

Responsible tutor

Training Coordinator & Tutor
Zoe Mousia
Koni Grob or Jose-Angel Garde Belz
Jan Arnaut
Bernard Hegarty or Katrin Kempf

15:30 – 16:00

Module 3: Quality Assurance System and Limitations of Third-Party systems



Training objective / subjects covered

To inform the participants the components of a Quality Assurance System and how to evaluate its adequateness compared to the nature of the activities performed (e.g. stage of supply chain, complexity of the product)

To present and discuss quality assurance systems required by applicable legislation and authorization decisions, self-monitoring and co-responsibility on the part of operators with practical examples and discuss the use of the third-party systems such as BRC and limitations

Content

Regulation (EC) No 2023/2006 (compliance with requirements of articles 5, 6 and 7) information on tools such as Industrial guides on GMP, EU and national competent authorities' guidelines.

Quality assurance systems for self-monitoring (practical examples)

Method of training

Lecture 2.2

Responsible tutor

Training Coordinator & Tutor

Jan Arnaut

Zoe Mousia

16:00– 16:30// Coffee break

16:30 – 17:15

Module 2: Practical group Exercise: Preparation of checklist for different stages of supply chain



Training objective / subjects covered

The objective is to prepare participants to create different checklists for business operators of different stages of supply chain (e.g.: border, wholesalers, distributors, producers of multimaterials with adhesive, ...) and to share professional experience with participants. The audience will be divided into groups in order to work on different case studies.

Method of training

Working groups
Exercise

Responsible tutor

Training Coordinator & Tutor

Zoe Mousia

Jan Arnaut

Bernard Hegarty or Katrin Kempf

Koni Grob or Jose-Angel Garde Belz

20:00 // Dinner / social event

DAY 3: Official Control of Food industry (FCM user)

9:00-12:30

Module 2: Visit of Food industry (FCM user)



Training objective / subjects covered

The specific objective is to discuss the harmonised application of FCM requirements by the food industry laid down in the Regulation (EU) No 1935/2004 and Food law 178/2002.

To know how to check compliance of FCM in a food industry regarding the use of FCM (food packaging, food production equipment) in terms of DoCs, traceability, etc. The objective of the visit is to focus on food processing equipment not only packaging (view on FCM) and not deal with Hygiene aspects.

The visit will be divided into 5 parts:

Introduction of the food industry; introduction of the HACCP/QMS systems, control plan and documentation regarding the use of FCMs (packaging, food processing equipment)

Working group: The audience will be divided into 3 groups in order each group will visit the food production industry on the basis of the checklist requirements created the day before (DoCs/conformity certificates by the suppliers, traceability, in-house control etc.) Each group will fill in form the checklist during the visit.

Visit: Practical training of inspectors focusing on food contact materials use (packaging and food processing equipment) in food production premises

Restitution on the audience: presentation of the 3 checklists in front of the audience

Discussion: On the basis of the observations made during the morning, discussions and questions on the harmonisation of GMP practices and inspection in EU Member states

Synthesis of observations by small groups of trainees

- Discussion on the compliance control of FCM used (packaging and food processing equipment) of the Food company (FCM control is included in HACCP system)
- Discussion on FCM specification according to the intended use, and received DoCs, information regarding the FCM, in-house control)de
- Observation of Good Manufacturing Practices (e.g. FCM storage and use (Food packaging)
- Observation of traceability of Food Contact Materials

Method of training

Visit of a food industry establishment

Discussion with the Food

Businesses Operator representative at the company

Responsible tutor

Training Coordinator & Tutor

Zoe Mousia

Jan Arnaut

Eugenia Lampi or Milada Sycova

12:30 – 13:30 // Lunch break

13:30 -14:00

Module 2: Discussion of official control in Food Industry (FCM user)



Training objective / subjects covered

Observation, discussion and recording of comments on the application of Reg. (EC) No 1935/2004 and Regulation (EC) No 2023/2006 and the specific measures apply to them.

Result of the discussion will enable inspectors to make corrections on the checklist based on the experience during the field visit and to understand the importance of use of checklists during inspections.

Method of training

Discussion

Responsible tutor

Training Coordinator & Tutor

Zoe Mousia**Eugenia Lampi or Milada Sycova**

14:00 – 14:30

Module 2: Preparation of checklists

OCP09

Training objective / subjects covered

Conclusion of the participants on the preparation by competent authorities of checklists for inspectors;

Preparation and delivery of a harmonised checklist as a support to the group for the next audits, depending on the material (ceramic, plastic) and the order in the supply chain.

Method of training

Lecture 3.1

Responsible tutor

Training Coordinator & Tutor

Eugenia Lampi or Milada Sycova**Zoe Mousia**

14:30 – 15:30

Module 2: Inspection of DoC and SD

OCP10

Training objective / subjects coveredObjectives of the session:

Learn how to assess DoC's (completeness and correctness) and compare with legislative requirements for the intended use. Exchange of experience between participants

- Introduction of Declarations of Compliance (DoC), specific requirements for DoCs, (explanations regarding the sum of information should be included in it)
- Introduction of Supporting Documentation (SD) of compliance and explanations of what consists the supporting documentation.
- Specific provisions for SD in the EU legislation The SD to demonstrate compliance: Aim of the SD; SD for Compliance to established limits and requirements (positive lists, Regulated tests; SD for Compliance to general requirements; (art. 3 Reg (EC) 1935/2004)
- Assessment of DoC and SD
- Content of the session: discussion on examples of DoC's covering Plastic FCM.
- Specific provisions for DoC on specific materials or topics (it will be specified the aim of DoC, who has to issue them (references to EU guidance document) and to whom are addressed.
- Introduction of the Commission's '**Guidance on information** in the supply chain.

Method of training

Lecture 3.2

Discussion

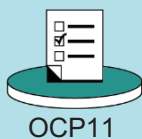
Responsible tutor

Training Coordinator & Tutor

Eugenia Lampi or Milada Sycova**Zoe Mousia**

15:30-16:30

Module 2: Inspection of DoC and SD



Training objective / subjects covered

To propose about 10 examples to the audience on Inspection and check of DOC and SD and to allow share of experience between participants, after delivering the correct answer.

- On the basis of 5 DOCS from ceramics, plastic, regenerated cellulose film, recycled plastics, Active and Intelligent Materials and articles) participants will answer to some quick questions to assess them and to answer if the Documents fulfilled the requirements (issuer, specific information, identification data, statement of compliance, date of declaration, information on restricted substance, intended uses, statement of compliance for functional barrier
- On the basis of 5 SD (kind of information should be contained in the SD, accessibility of the SD, establishment of limit and requirements); participants are asked to answer to 5 questions, before delivering the answers.
- The quiz is designed with examples (DOC, SD) provided by the team of experts (based on theirs experiences)

Method of training

Quiz

Responsible tutor

Training Coordinator & Tutor

Eugenia Lampi or Milada Sycova

Zoe Mousia

16:30-17:00 // Coffee break

17:00-17:30

Module 4: National Control Plan



Training objective / subjects covered

The main objective is to inform the officers about setting risk-based national control plans on food contact materials set up and how it could influence their daily work.

The specific objectives are:

- To know the basic principles of official control in the EU
- To know legal basis and purpose to set up national plans for food contact materials
- To know the general content of food contact materials national plans according to the stage
- To define orientations to set up national plans for food contact materials

The content will include:

- Setting up national risk-based control plans on food contact materials (Reg. (EU) No 625/2017)
- Organisation and structure of official controls performed to ensure the verification of compliance of FCM (simplification)

Method of training

Lecture 3.3

Questions & answers

Responsible tutor

Training Coordinator & Tutor

Milada Sycova or Eugenia Lampi or

Zoe Mousia

17:30-18:00

Module 4: Setting up FCM plan



NCP02

Training objective / subjects covered

A brainstorming is organised to ask participants the different considerations and criteria to take into account for setting up an FCM plan.

- Which stages are to be inspected?
- Direct and indirect checks
- Inspections at the different stages or not
- Orientations for setting up of national plans :
- Criteria to decide which materials, articles and substances to check in priority?
- Frequency
- Resources controls
- Risk to human, animal or plant health, animal welfare or the environment

Method of training

Brainstorming Discussion
Questions & answers

Responsible tutor

Training Coordinator & Tutor
Eugenia Lampi or Milada Sycova
Zoe Mousia

18:00-18:30

Module 4: New Official Regulation (EU) No 2017/625



NCP03

Training objective / subjects covered

The objective is to inform the audience on the New Regulation (EU) No 2017/625 t be applicable on December 2019.

- Changes introduced via Official Controls Regulation (EU) No 2017/625 related to FCM
- Organisation of official controls, collaboration with MS etc.
- information on RASFF and IMSOC : including benefits, drawbacks and results
- Demonstration of homepage
- Information on laboratories

Method of training

Lecture 3.4
Questions & answers

Responsible tutor

Training Coordinator & Tutor
Zoe Mousia

20:00 // Dinner in traditional restaurant

DAY 4: Laboratory control and follow up and closing meeting

08:30-09:15

Module 4: FCM Sampling Laboratory



NCP04

Training objective / subjects covered

To inform the audience on FCM sampling and on Laboratory control (conditions of migrations tests, difficulties)

To inform how they can benefit from the Laboratory expertise on the daily work for the control of FCM.

Content

Regulation 10/2011 and other specific measures (as Directive 84/500-ceramic, etc)
Art. 34–42: Sampling, analyses, tests, Diagnoses of new Regulation (EU) No 2017/625

Assessment of compliance with migration limits, migration testing rules, reduction factors, analytical methods (Large number of substances-mixtures of them, complex matrices, no standardised methods for all substances(no methodology/guidelines/references substances), sensory analysis (organoleptic) capacity of labs limited (for verification of compliance), expertise, difficulties in analysis samples (with or no papers such as DoC, SD)

Method of training

Lecture 4.1

Questions & answers

Responsible tutor

Training Coordinator & Tutor

Eugenia Lampi or Milada Sycova

Zoe Mousia

09:15-10:15

Module 4: Follow-up



NCP05



Training objective / subjects covered

Techniques and practices to follow-up on non-compliances (penalty, sanctions, second checks, based on risk)

New reg. 625/2017 of techniques & practices to follow up on non-compliances (e.g. article 13 (written records of official controls), article 131, 132 (IMSOC-information management system for official controls and 138 actions in the event of non-compliance etc.))

Quiz on some different examples of follow-up on non-compliances: recall or destruction /sanction.

Financial penalties targeting fraudulent behaviour must reflect the economic advantage of the perpetrator or a percentage of his/her turnover) and discussion of the approach of non-compliances.

Method of training

Lecture 4.2 & Quiz

Questions & answers

Responsible tutor

Training Coordinator & Tutor

Eugenia Lampi or Milada Sycova

Zoe Mousia

10:15-10:45 // Coffee break

10:45 – 11:00

Discussion



GEM05

Training objective / subjects covered

Discussion in plenary session on the whole content of the training, moderated by the training coordinator.

Review trainees' questions and expectations

Method of training

Discussion

Responsible tutor

Training Coordinator & Tutor

Zoe Mousia

Eugenia Lampi or Milada Sycova

11:00 – 11:15

Dissemination



GEM06

Training objective / subjects covered

The training coordinator will share with the audience relevant documents (legislation, guidance, scientific opinions) in order to support the audience to disseminate information not theirs colleagues.

Method of training

Discussion

Question and answers

Responsible tutor

Training Coordinator & Tutor

Zoe Mousia

Eugenia Lampi or Milada Sycova

11:15 – 11:45

Post-test (Repetition of day 1) and answers



GEM07

Identify the success of the training course and the difficulty of assessing Food Contact Material.

Method of training

Test

Responsible tutor

Training Coordinator

Zoe Mousia

Eugenia Lampi or Milada Sycova

11:45– 12:00

Closing of the Training



GEM08

Remarks by the trainees

Conclusions regarding the FCM programme

Method of training

Discussion

Responsible tutor

Training Coordinator

Zoe Mousia

Eugenia Lampi or Milada Sycova

12:00-12:30

Evaluation and delivery of training certificates



GEM09

Evaluation of the Training on line

Distribution of training certificates, group photo

Method of training

Closing ceremony

Responsible tutor

Training Coordinator

Zoe Mousia

Eugenia Lampi or Milada Sycova

12:30 – 13:30 // Lunch at the Hotel / After 13:30 // Free Time + Transfer to airport