

SEMINAR

23 - 24 OCTOBER 2017

BRUXELLES

HOTEL AMIGO
RUE DE L'AMIGO

BELGIUM

INTRODUCTION TO FOOD CONTACT LEGISLATION IN THE USA

The seminar offers training regarding the main characteristics of **the discipline of food contact materials for the US market.**

The first day of the seminar will be dedicated to an overview of the US **Food and Drug Administration**, one of the largest American Federal Agencies, with the objective of enabling a familiarisation regarding their legislative approach covering the various food contact materials and articles and their intended use, enabling a further insight into the concepts, the trends and evolution of the FDA food contact discipline.

The procedures for evaluating and notifying new substances with the FDA will be dealt with in a specific focus.

The differences between European and American legislation will be tackled on the second day. Lastly, the seminar will present **a series of practical cases showing the requisites and the requirements laid down by US legislation** for food contact materials and articles.

PROMOTED BY



English-Only

PROGRAM

23 OCTOBER

09.00 - 09.30	REGISTRATION
09.30 - 11.00	SEMINAR
11.00 - 11.30	COFFEE BREAK
11.30 - 13.00	SEMINAR
13.00 - 14.15	LUNCH IN HOTEL
14.15 - 17.30	SEMINAR

! PACKAGING MEETING SRL
RESERVES THE RIGHT
TO MAKE ANY MODIFICATIONS
TO THE PROGRAM EVEN DURING
THE HOLDING OF THE SAME

SPEAKERS

- **Deborah Attwood**
Steptoe & Johnson
- **Mitchell Cheeseman**
Steptoe & Johnson
- **Kevin C. Kenny**
Decernis

1. U.S. FDA FOOD CONTACT FUNDAMENTALS

Overview of the US legal and regulatory requirements for food and food packaging

- General Principles
- Food Additive Petitions (FAP's)
 - 1958-1999 – primary way to add new FCS
- FDA No Objection Letters
- Threshold of Regulation (ToR) Exemptions
- Other Exemptions
 - Basic Resin Doctrine
 - Functional Barrier
 - Housewares
 - Mixtures
 - Prior Sanction
 - No Migration
 - Generally Recognized as Safe (GRAS)
 - | Final GRAS Rule
 - | Self GRAS Determination
 - | GRAS Notification
- Opinion Letters

2. CODE OF FEDERAL REGULATIONS (CFR) - 21 CFR PARTS 174-186

- General Structure
 - GRAS, Prior Sanction, Flavors, Colorants
 - Incorporations by Reference
 - Food Types and Use Conditions
- 21 CFR 175 -Adhesives & Coatings
- 21 CFR 176 -Paper & Paperboard
- 21 CFR 177 -Polymers
- 21 CFR 178 -Adjuvants, Production Aids, Sanitizers (includes Antimicrobials, Antioxidants, Colorants, Lubricants, Stabilizers, Woods, Waxes)
- 21 CFR 179 Irradiation

3. FOOD CONTACT NOTIFICATIONS (FCN's)

- Definitions, Advantages, Disadvantages
- FCN Process
- FCN Data Requirements
- Deficiency Letters
- FDA vs. EPA:
 - Environmental Assessments
 - Categorical Exclusions
 - FDA Guidance
- Infant Exposure
- List of Effective FCNs
- Emergence of New Safety Data

4. CONDUCTING A SAFETY EVALUATION

PART I: THE EXPOSURE ASSESSMENT

- Information needed for the exposure assessment
- Methods for conducting the exposure assessment
- Using default assumptions and market data
- Differences with the EU

English-Only

PROGRAM

24 OCTOBER

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5. COMPARISON: EU VS. US SYSTEMS

- Monomer vs. Polymer Regulation
- Positive List vs. Usage Limitations
- Plastic vs. Other Substrates
 - Regulation vs. Directive
 - Federal vs. Member State Legislation + Mutual Recognition
- Impurities vs. NIAS
- Mutual Recognition between FDA and EU
 - Regulations?
 - Risk Assessment?
 - | Migration modeling
 - | Food material use factors
 - | Exposure models (Matrix, Facet)

6. CONDUCTING A SAFETY EVALUATION PART II: THE SAFETY ASSESSMENT

- Safety standard and standard of review
- FDA's toxicology recommendations
- The Threshold of Toxicological Concern and read-across
- Sources of toxicology data

7. PRACTICAL CONSIDERATIONS

- Good Manufacturing Practice
 - US Approach
 - Other Quality tools: e.g., ISO 9001, HACCP, etc.
- Supply Chain Management
 - Definitions: Food Contact Substance vs. Material vs. Article
 - NDAs
 - Questionnaire do's and don'ts
- Public Relations Challenges
 - NGO Petitions to Delist: Perchlorates, Perfluoroalkyl-Containing Compounds, Phthalates
 - Publicity vs. Science
 - Recalls
- Specific Materials
 - Active and Intelligent Packaging
 - Printing Inks
 - Nanomaterials
 - Biocides
 - Recycling
- Federal vs. State
 - CAL Prop 65 – NSRLs/MADL
 - Other State Actions
 - Trump Administration
- Food Safety Modernization Act (FSMA)
 - Introduction
 - Foreign Supplier Verification (FSV) Requirements

8. STRATEGIES FOR INNOVATION

- The US: choosing shortest route to market
- Other Markets
 - Canada
 - Mexico
 - Other Markets which accept US and EU clearances

PARTICIPATION FEE

■ **700,00**
EURO NO VAT
2 DAYS

The registration fee includes:
 participation to the seminar,
 coffee breaks, lunches
 and speakers minutes.

■ The seminar **“Introduction to food contact legislation in the USA”** will be held the 23-24 October 2017 at the HOTEL AMIGO - RUE DE L'AMIGO - Bruxelles - Belgium.

SEMINAR attendees may take advantage of a reduced accommodation rate.

■ **REGISTRATION.** Send via fax to n. +39 (0)2 58319677 or via e-mail to the address formazione@istitutoimballaggio.it the registration form filled in full and signed as well as a copy of the payment.

■ **PAYMENT.** Please transfer the participation fee to the following bank account: Packaging Meeting Srl Consulenza & Formazione - Unicredit Banca Ag.2, Milano - IBAN: IT16J0200801602000004255458 - Swift code: UNCRITMM - VAT and Tax Code n. IT12464120158.

■ **SEMINAR SECRETARY.**

Phone +39 (0)2 58319624 - E-mail: formazione@istitutoimballaggio.it

REGISTRATION FORM

It is possible to fill in every single field by positioning the mouse directly on the pdf file

INTRODUCTION TO FOOD CONTACT LEGISLATION IN THE USA - 23/24 OCTOBER 2017 - Bruxelles

COMPANY

Street City Zip Code

Telephone/fax e-mail (for invoices)

Certified mail

VAT number Tax Code

Having read and accepted the “information and general conditions” I/we ask to register for the - INTRODUCTION TO FOOD CONTACT LEGISLATION IN THE USA - 23-24 October 2017 - Bruxelles - Belgium

Mr. Mrs.

Name Surname

Role/Rank

E-mail of participant(s)

Cancellation policy: any cancellation should be sent to the offices of Packaging Meeting Srl Consulenza & Formazione via registered letter or fax. Cancellations that reach the organizer's offices 3 full working days prior to the start of the Seminar will be reimbursed. No reimbursements will be granted for cancellations which reach the organizer's offices outside this deadline.

“To protect the right of privacy, it be made known that the compiling of the following document implies your consent so that the data contained in the same be registered by the Istituto Italiano Imballaggio and by Packaging Meeting Srl for the sole purpose of keeping you informed of their institutional activities, before which you may exercise your rights as under art. 13 of Decreto Legislativo 196/2003”.

Date

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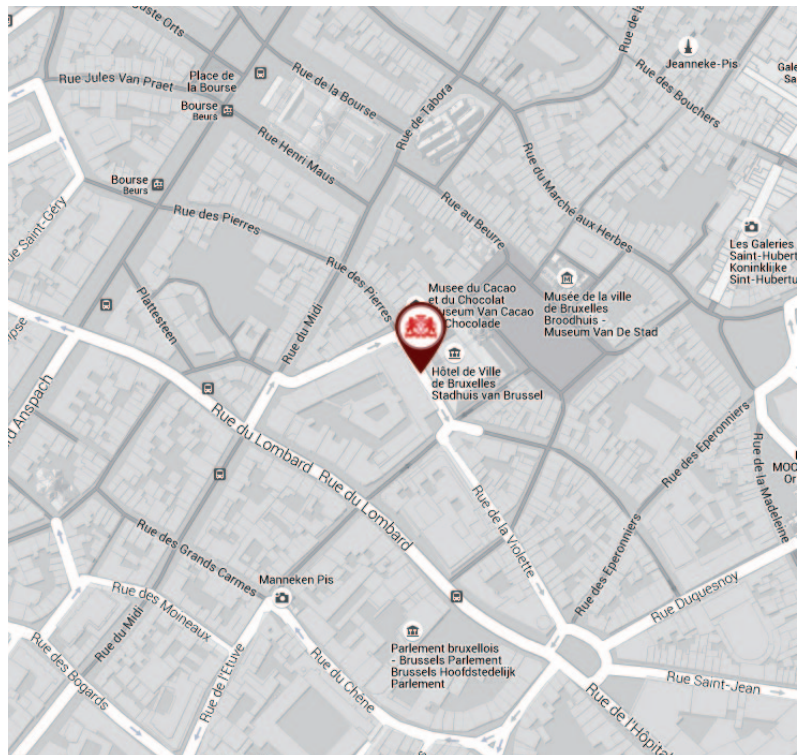
BELGIUM

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HOW TO REACH US

■ **Hotel Amigo** stands at the crossroads of the historic Ilot Sacré area and the antiques district of Le Sablon. We're a short stroll from the Grand Place, the hub of European politics and the hip boutiques on Rue Dansaert.



HOTEL RESERVATION

■ A special accommodation rate will be applied to seminar attendees

SINGLE CLASSIC: 219 € PER NIGHT



RESERVATION FORM



ROCCO FORTE
HOTELS



INDIVIDUAL CALL-IN SHEET

Please fill out this form in capital letters and return it by fax or by email
no later than **23.09.17**
REF: ISTIT231017

Arrival date: 23.10.17 Departure date : 25.10.17
CHECK-IN AFTER 3PM – TO BE LEFT BEFORE NOON

CANCELATION POLICY:

Until 7 days before arrival: cancellation is free of charge
Between 7 days before arrival and the arrival date, the full amount of each room night
will be invoiced

PERSONAL INFORMATION

FIRST NAME _____ LAST NAME _____
NATIONALITY _____
ADDRESS _____
CITY _____ COUNTRY _____
TELEPHONE _____ FAX _____
E-MAIL _____

SINGLE CLASSIC AT EUR 219

This Rate includes vat, service and breakfast
City tax is excluded (€9.28 per room per night)

SMOKING

NON SMOKING

ARRIVAL DATE _____ FLIGHT N° _____ ARRIVAL TIME _____
DEPARTURE DATE _____ FLIGHT N° _____ DEPARTURE TIME _____

CONFIDENTIAL INFORMATION

PASSEPORT N° _____
CREDIT CARD N° _____ EXPIRY DATE _____
CREDIT CARD HOLDER _____
MASTER CARD AMERICAN EXPRESS VISA AUTRE



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BRUSSELS

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