

PRACTICAL FOOD LAW SEMINAR (BRUSSELS) | 3 – 4 OCTOBER 2018

DAY ONE: Wednesday, 3 October 2018

INSTRUCTORS: Melvin S. Drozen, Nathalie Henin, Christophe Leprêtre, Katia Merten-Lentz, Manon Ombredane, Evangelia C. Pelonis, and Frederick A. Stearns

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| 8:00 – 8:30 | Registration/Continental Breakfast |
| 8:30 – 8:45 | Welcome and Introductory Activities
<i>Katia Merten-Lentz, Partner</i> |
| 8:45 – 10:30 | Statutory Framework, Jurisdiction, and Adulteration I - II
<i>Frederick A. Stearns, Partner</i> <ul style="list-style-type: none"> • Federal Food, Drug, and Cosmetic Act and Related Statutes • Interstate Commerce • Classification as Food, Drug, Dietary Supplement, Cosmetic • “Poisonous”; Added/Deleterious; “May Render Injurious”; “Ordinarily Injurious” • Intentional Additives (Food and Color Additives, Pesticide Chemicals, Food Contact Materials) • GRAS Status • Contrast with E.U. – <i>Christophe Leprêtre, Regulatory and Scientific Affairs Counselor</i> |
| 10:30 – 10:45 | Break |
| 10:45 – 12:00 | Adulteration III and IV
<i>Melvin S. Drozen, Partner</i> <ul style="list-style-type: none"> • Delaney Clause • Unintentional Additives (<i>e.g.</i>, Food Contact Substances, Pesticide Residues, Environmental Contaminants) • Dietary Ingredients • Filth • Unfit for Food, Emergency Permit Exemptions, and Good Manufacturing Practice/HACCP/HARPC • Contrast with E.U. – <i>Katia Merten-Lentz, Partner</i> |
| 12:00 – 13:15 | Lunch (<i>provided by Keller and Heckman LLP</i>) |
| 13:15 – 15:15 | Food Safety Modernization Act (FSMA) Requirements
<i>Evangelia C. Pelonis, Partner</i> <ul style="list-style-type: none"> • Hazard Analysis and Risk-Based Preventive Controls (HARPC) • Foreign Supplier Verification Program (FSVP) • Contrast with E.U. – <i>Nathalie Henin, Ph.D., EMBA, Scientific and Regulatory Advisor</i> |
| 15:15 – 15:30 | Break |
| 15:30 – 16:45 | FDA Inspections and Import/Export Issues
<i>Frederick A. Stearns, Partner</i> <ul style="list-style-type: none"> • Managing Inspections, Record Review and Photographs • Recordkeeping and Retention • Import/Export Procedures and Requirements • Contrast with E.U. – <i>Manon Ombredane, Legal Consultant</i> |
| 17:00 – 18:30 | Networking Cocktail Reception |

PRACTICAL FOOD LAW SEMINAR (BRUSSELS) | 3 – 4 OCTOBER 2018

DAY TWO: Thursday, 4 October 2018

INSTRUCTORS: Caroline Commandeur, Melvin S. Drozen, Nathalie Henin, Richard F. Mann, Katia Merten-Lentz, Manon Ombredane, Evangelia C. Pelonis, and Frederick A. Stearns

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| 8:00 – 8:30 | Continental Breakfast |
| 8:30– 10:15 | <p>Mandatory Label Requirements and Nutrition Labeling
<i>Melvin S. Drozen, Partner</i></p> <ul style="list-style-type: none"> • Contrast with E.U. – <i>Nathalie Henin, Ph.D., EMBA, Scientific and Regulatory Advisor</i> |
| 10:15 – 10:30 | Break |
| 10:30 – 12:00 | <p>Nutrient Content Claims, Fresh, Natural, Organic, Health Claims, GM Labeling
<i>Evangelia C. Pelonis, Partner</i></p> <ul style="list-style-type: none"> • Contrast with E.U. – <i>Katia Merten-Lentz, Partner</i> |
| 12:00 – 12:45 | Working Lunch (<i>provided by Keller and Heckman LLP</i>) |
| 12:45 – 14:00 | <p>Approving, Defending and Challenging Food Advertising Claims
<i>Richard F. Mann, Partner</i></p> <p>When Is a Claim -</p> <ul style="list-style-type: none"> • Constitutionally Protected? • Non-Actionable Puffery? • Material? • Substantiated Adequately? • Deceptive/Misleading? • False? • Unfair? • Banned? • Contrast with E.U. – <i>Caroline Commandeur, Junior Legal Consultant</i> |
| 14:00 – 14:15 | Break |
| 14:15 – 14:45 | <p>Related Issues - California Proposition 65 and Class Action Lawsuits
<i>Richard F. Mann, Partner</i></p> |
| 14:45 – 15:45 | <p>FDA Enforcement Tools
<i>Frederick A. Stearns, Partner</i></p> <ul style="list-style-type: none"> • Recalls: Overview and Tips for Handling • Enforcement Discretion, Warning Letters, Administrative Detention, Suspension of Food Facility Registration, Seizures, Injunctions, Criminal Prosecutions, Publicity • Contrast with E.U. – <i>Manon Ombredane, Legal Consultant</i> |
| 15:45 | <p>Wrap Up Discussion and Seminar Adjourns
<i>Keller and Heckman LLP attorneys</i></p> |