A REGULATORY UPDATE ON ANIMAL FEED & FEED ADDITIVES IN THE EU, CHINA & USA

Application to Register

3 & 4 December 2012
Conference Ref: V12-8012

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To Register

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If you have NOT received confirmation seven days after registering, please contact Registration Department.

Registration Information

Dates
3 & 4 December 2012

Times
3 December 2012 Start: 09.30 – Finish: 17.00
Drinks Reception Start 17.00 - Finish 18.00
4 December 2012 Start: 09.15 – Finish: 16.30

Registration & Coffee
3 December 2012 09.00

Venue and Accommodation
The Rembrandt Hotel, 11 Thurloe Place,
London SW7 2RS
Hotel Tel: +44(0)20 7589 8100.
Hotel Fax:+44(0)20 7225 3476.
Email: ***reservations_rembrandt@sarova.co.uk***

Subject to availability, a limited number of bedrooms have been reserved at the hotel at a special rate. **All bookings should be made directly with the hotel or online at *www.sarova.com/rembrandt*, quoting promo code 'manforum'.**

Directions
Opposite V&A Museum. Nearest Underground station: South Kensington.

Fee
£1270 + VAT (If applicable). The fee includes course documentation as well as mid-session refreshments, lunch and drinks reception. Invoice and confirmation will be forwarded to you.

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Discounted Rates
Available on application for personnel from non-profit making organisations and registered charities.
Group discount available on request

Cancellation Policy:
Over 14 days prior to the Seminar: Cancellation fee of £75. 7/14 days prior to the Seminar: 50% of the fee. Fewer than 7 days or if no notification received: Registrant liable to pay FULL seminar fee.
NB: Cancellations must be received in writing by *registrations@management-forum.co.uk.*
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Exhibition spaces and promotional opportunities will be available at this meeting.
For further information please contact **Vicki Elliot**
(email: vicki@management-forum.co.uk)

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Annual Conference

A REGULATORY UPDATE ON ANIMAL FEED & FEED ADDITIVES IN THE EU, CHINA & USA

Exhibition opportunities available

Increase your networking by attending the Drinks Reception

Programme to Include:

- An Update on Regulation EC (No):1831/2003 on Additives for Use in Animal Nutrition
- EU Assessment of Feed Additives and Application Handling
- The Role of the EU Commission and Comitology
- Mycotoxin Binders and Other New Categories of Feed Additives
- Differences Between Feed, Feed Additives and Veterinary Products
- Strategic Options for Animal Nutrition Products in the EU
- US FDA Approaches to the Regulation of Feed Additives
- The New Legal Framework for Feed Additives in China
- Statistics and Good Study Design
- Feed Additive Dossiers for EU, China and the USA

To be Chaired by:
Dr Elinor McCartney, Director, Pen & Tec Consulting S.L, Spain

With an International Panel of Speakers:
Diederik Standaert, Directorate General of Animals, Plants and Food – Service Food, Feed and Other Consumer Goods, Belgium Authorities, Belgium
Miguel-Angel Granero-Rosell, Unit G1, Animal Nutrition, DG Health and Consumers, EU Commission
Dr Claudia Roncancio Peña, European Food Safety Authority (EFSA)
Dr Lucy Waldron, LWT Animal Nutrition, New Zealand
Dr Douglass Oeller, President, Douglass Oeller Consulting Inc. USA
Ruud Bremmers, Regal BV, The Netherlands

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3 & 4 December 2012
The Rembrandt Hotel, London

INTRODUCTION

Meeting current and future regulatory requirements for feed and feed additives in the EU and other important markets such as China and the USA are major challenges for businesses operating in these sectors. This conference will review EU legislation, examining both procedures and data requirements, and discuss to what extent EFSA-compliant data can be used to meet new regulatory approaches in China and the USA.

As a result of various food scandals in the 1990s the EU published the White Paper on Food Safety in 2000, and in 2002, created EFSA (European Food Safety Authority). Today, the EU is the highest-value food market in the world and is reputed to have the toughest regulatory environment governing the food chain, especially with respect to animal feeding. In the last decade the EU feed additive regulation (EC Nº 1831/2003) replaced the existing feed additive Directive 70/524/EEC and introduced a new system for assessing feed additive dossiers. The new evaluation procedure involves the EU Commission and the EURL (European Union Reference Laboratory), EFSA and the Standing Committee on the Food Chain and Animal Health, which includes delegations from 27 EU Member States ('Comitology').

Regulation (EC) Nº 1831/2003 re-categorised feed additives, created new functional groups, and re-classified amino acids, silage agents and urea as feed additives. Functional groups have been expanded to include new types of feed additives, such as mycotoxin inactivators with a new class of feed hygiene additives under discussion. Antibiotic growth promoters were prohibited in the EU from January 2006 and although coccidiostats remain as feed additives, maintaining approvals under EU legislation presents considerable challenges for FBOs (Feed Business Operators). A re-evaluation process of older feed additives is underway, involving around 500 dossiers, and the EU has prohibited feed additives where no re-evaluation dossier was submitted or which failed to obtain a positive EFSA opinion. The recent EU feed regulation (EC Nº 767/2009), the feed material register and the EU catalogue of feed materials have improved transparency in feed labelling and marketing, while allowing certain physiological and functional claims to be made.

Depending upon the intended use, the US FDA may regulate a product added to animal feed as either a drug of a feed additive. In either case, the Food Drug and Cosmetic Act requires the sponsor to obtain FDA approval or GRAS recognition prior to marketing these products. In the past, FDA has followed a policy of enforcement discretion to allow marketing of unapproved feed additives if the substance has been evaluated using the AAFCO feed ingredient definition process and listed in the Official Publication. The FDA is now encouraging sponsors to follow the food additive petition approval process for new products.

In 2012 the Chinese Ministry of Agriculture introduced new guidance and legislation on feed additives, adopting some aspects of EU/EFSA, other aspects of USA FDA, and some uniquely Chinese approaches in the area of animal nutrition.

For these reasons many companies manufacturing or marketing feed additives wish to address, as far as possible, the regulatory requirements of EU, Chinese and US authorities in a single project.

Workshop exercises will offer delegates the opportunity to work together in an informal environment to solve specific regulatory problems.

WHO SHOULD ATTEND?

Regulatory, Business Development, Strategic Marketing Managers and Feed Business Operators responsible for animal feed and feed additives in global markets. Registration Managers, Product Managers, R&D Scientists and Project Managers will also find this meeting beneficial, together with Senior Managers seeking an update on current trends in the regulation of products destined for animal nutrition in Europe, China and the USA.

TO BE CHAIRED BY:

Dr Elinor McCartney, Director, Pen & Tec Consulting S.L., Spain

SPEAKERS

Diederik Standaert, Directorate General of Animals, Plants and Food – Service Food, Feed and Other Consumer Goods, Belgium Authorities, Belgium
Dr Claudia Roncancio Peña, European Food Safety Authority (EFSA)
Miguel-Angel Granero-Rosell, Unit G1, Animal Nutrition, DG Health and Consumers, EU Commission
Dr Lucy Waldron, LWT Animal Nutrition, New Zealand
Dr Douglass Oeller, President, Douglass Oeller Consulting Inc. USA
Ruud Bremmers, Regal BV, The Netherlands

Day One — 3 December 2012

09.30 ▶ **Welcome and Introduction**
Dr Elinor McCartney, Pen & Tec Consulting

09.45 ▶ **Update on Regulation (EC) Nº 1831/2003 on Additives for Use in Animal Nutrition**
- Key elements of the EU authorisation procedure for feed additives
- EURL - EFSA fees
- Mycotoxin binders : state of play
- Borderline additives – biocidal products
- Re-evaluation of existing feed additives: progress to dates

Diederik Standaert, Belgian Authorities

10.45 ▶ **Discussion, Questions & Answers**

11.00 ▶ **Coffee**

11.30 ▶ **Assessment of Feed Additives and Application Handling**
- EFSA Feed Unit structure
- Application handling – administrative and technical
- The roles of the EFSA Secretariat, Working Groups, Plenary Meetings
- Recipes for success

Dr Claudia Roncancio Peña, EFSA

12.30 ▶ **Discussion, Questions & Answers**

12.45 ▶ **Lunch**

13.45 ▶ **The Role of the EU & Comitology**
- Scope of EU legislation
- Differences between feed, feed additives & veterinary products
- Feed & feed additive claims – best practices

Miguel-Angel Granero-Rosell, EU Commission

14.45 ▶ **Discussion, Questions & Answers**

15.00 ▶ **Tea**

15.30 ▶ ***Workshop Session 1: Strategic Options for Animal Nutrition Products in the EU***
Led by Dr Elinor McCartney, Pen & Tec Consulting

16.45 ▶ **Discussion**

17.00 ▶ **End of Day One**

17.00 – 18.00 Networking Drinks Reception for Delegates and Speakers

Day Two — 4 December 2012

09.15 ▶ **Welcome and Review of Day One**
Dr Elinor McCartney, Pen & Tec Consulting

09.30 ▶ **The US FDA Approach to the Regulation of 'Feed Additives'**
- Legal framework
- US guidelines
- Recent changes
- Key differences from EU

Dr Douglass Oeller, Douglass Oeller Consulting Inc

10.30 ▶ **Discussion, Questions & Answers**

10.45 ▶ **Coffee**

11.15 ▶ **The Chinese Approach to Feed Additives**
- Legal framework
- Chinese guidance
- Recent changes
- Key differences from EU

Dr Elinor McCartney, Pen & Tec Consulting

12.15 ▶ **Differences of Feed/Feed Additives and Veterinary Products: Regulations and Practice**
Ruud Bremmers, Regal BV

12.45 ▶ **Discussion, Questions & Answers**

13.00 ▶ **Lunch**

14.00 ▶ **Statistics and Good Study Design**
- Common issues
- Ethical considerations
- Controlling costs
- Examples of trial design

Dr Lucy Waldron, LWT Animal Nutrition

14.45 ▶ **Tea**

15.15 ▶ ***Workshop Session 2: Project Management - Feed Additive Dossiers for EU, China & USA***
Led by Dr Elinor McCartney, Pen & Tec Consulting

16.15 ▶ **Discussion**

16.25 ▶ **Closing Remarks**

16.30 ▶ **Close of Forum**

A Certificate of Attendance for Professional Development will be given to each participant who completes the course.

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