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

Application to Register

9 & 10 December 2013
Conference Ref: V12-8013

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To Register

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Registration Information

Dates
9 & 10 December 2013

Times
9 December 2013 Start: 09.30 – Finish: 17.15
Drinks Reception Start 17.15 - Finish 18.15
10 December 2013 Start: 09.00 – Finish: 16.30

Registration & Coffee
9 December 2013 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.
www.sarova-rembrandthotel.com/location-local-attractions

Fee
£1275 + 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.
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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

MANAGEMENT FORUM
Celebrating 30 Years

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 procedures in relation to feed additive applications
- EFSA application handling and scientific evaluation
- The role of the EU Commission, the EURL and Comitology
- Mycotoxin binders and other new categories of feed additives
- EU legal classes – feedingstuffs, feed additives and veterinary medicinal products
- Basic statistics and good study design
- Strategic options for animal nutrition products in the EU
- US FDA approaches to the regulation of feed ingredients
- The legal framework for feed additives in China
- Managing feed additive dossier projects targeted at the 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, Belgian Authorities, Belgium
Ruud Bremmers, Regal BV, The Netherlands
Professor George Gettinby, Department of Statistics and Modelling, University of Strathclyde, UK
Dr. Marta Ponghellini, Veterinary & International Affairs, Unit G1, Animal Nutrition, DG Health and Consumers, EU Commission
Dr Claudia Roncancio Peña, Head of Feed Unit, European Food Safety Authority (EFSA)
Xiahong Wang, Director of Animal Feed Division, Department of Animal Production, Ministry of Agriculture, People's Republic of China
Dr. Kristi O. Smedley, Center for Regulatory Services, Inc. USA

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9 & 10 December 2013
The Rembrandt Hotel, London

INTRODUCTION

Meeting regulatory requirements for feed and feed additives in the EU and other key markets such as China and the USA are major challenges for businesses in the field of animal nutrition. This conference will review EU legislation, examining procedures and data requirements, and discuss to what extent EFSA-compliant data can be used to achieve approvals in China and the USA.

The EU has transformed its food legislation in recent years, creating EFSA (European Food Safety Authority) in 2002 and adopting a harmonised approach to food safety, "from farm to fork". The 2003 feed additive regulation introduced a central ("one door-one key") approval system for feed additives, involving the EU Commission, the EURL (European Union Reference Laboratory), EFSA and the Standing Committee on the Food Chain and Animal Health, with delegates from 28 Member States ('Comitology').

Regulation (EC) Nº 1831/2003 re-categorised feed additives and extended the scope to include amino acids, silage agents and urea. New classes of feed additives were added, e.g. mycotoxin inactivators, with feed hygiene additives under discussion. The EU completed its ban on antibiotic growth promoters in January 2006 and although coccidiostats remain as feed additives, maintaining approvals presents considerable challenges for FBOs (Feed Business Operators). Re-evaluation of around 500 feed additives started in 2010 and the EU is systematically prohibiting feed additives for which no re-evaluation dossier was submitted, or which fail EFSA's scrutiny. A new feed regulation, the feed material register and the catalogue of feed materials have improved transparency in feed labelling, while allowing some physiological and functional claims.

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

Informal workshops will enable delegates to work together to solve specific regulatory problems.

WHO SHOULD ATTEND

This forum gives a broad overview for regulatory, business development, strategic marketing managers and feed business operators responsible for animal nutrition products in global markets. Registration managers, product managers, R&D scientists and project managers will also find this meeting beneficial, together with senior managers seeking a "snapshot" of current regulatory trends feeds and feed additives 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
Ruud Bremmers, Regal BV, The Netherlands
Professor George Gettinby, Department of Statistics and Modelling, University of Strathclyde, UK
Dr Claudia Roncancio Peña, Head of Feed Unit, European Food Safety Authority (EFSA)
Dr. Marta Ponghellini , Veterinary & International Affairs, Unit G1, Animal Nutrition, DG Health and Consumers, EU Commission
Dr. Kristi O. Smedley, Center for Regulatory Services, Inc. USA
Xiahong Wang, Director of Animal Feed Division, Department of Animal Production, Ministry of Agriculture, People's Republic of China

Day One — 9 December 2013

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

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

Diederik Standaert, Belgian Authorities

11.00 ▶ **Discussion, Questions & Answers**

11.15 ▶ **Coffee**

11.30 ▶ **Challenges in a Choppy Sea – Navigating a Dossier Through EFSA**
- Best practices
- Unpleasant surprises
- Advice for a successful outcome

Ruud Bremmers, Regal BV

12.30 ▶ **Discussion, Questions & Answers**

12.45 ▶ **Lunch**

13.45 ▶ **Basic Statistics and Good Study Design (Includes Answers to Several Mysteries)**
- What is a replicate and how many do I need?
- ANOVA and other simple statistical approaches
- How do I write a good study design?
- Are power calculations essential and where can I learn more?
- When do I include a positive control?
- When may I need to use an EFSA-compliant meta-analysis and who can help me?

Professor George Gettinby, University of Strathclyde

15.15 ▶ **Discussion, Questions & Answers**

15.30 ▶ **Tea**

15.45 ▶ ***Informal Workshops:***
- Strategic options for animal nutrition products in the EU
- Managing EU dossier projects – best practices
- Statistics is fun

Led by Dr Elinor McCartney, Pen & Tec Consulting

17.15 ▶ **End of Day One**

17.15 – 18.15 Networking Drinks Reception for Delegates and Speakers

Day Two — 10 December 2013

09.00 ▶ **Review of Day One**
Dr Elinor McCartney, Pen & Tec Consulting

09.15 ▶ **The Role of the EU & Comitology**
- Scope of EU feed additive legislation – in or out of scope?
- Differences between feeds, feed additives & veterinary products
- Feed & feed additive claims – best practices
- Post-EFSA opinion – Comitology
- When to consult the EU Commission
- What's new and in the pipeline

Dr. Marta Ponghellini, EU Commission

10.15 ▶ **Discussion, Questions & Answers**

10.30 ▶ **Coffee**

11.00 ▶ **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, European Food Safety Authority

12.00 ▶ **Discussion, Questions & Answers**

12.30 ▶ **Lunch**

13.30 ▶ **The US FDA Approach to the Regulation of Feed Ingredients**
- Legal and regulatory framework
- Authorising pathways for feed ingredients
- Recent changes
- Key differences from EU

Dr. Kristi O. Smedley, Center for Regulatory Services

14.30 ▶ **Discussion, Questions & Answers**

14.45 ▶ **Tea**

15.00 ▶ **The Chinese Approach to Feed Additives**
- Legal framework
- Chinese guidance documents
- Recent changes

Xiahong Wang, Ministry of Agriculture

16.00 ▶ **Discussion, Questions & Answers**

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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