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A Regulatory Update on Animal Feed and Feed Additives in the EU, USA and China

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Date and venue

6-7 December 2018 **Ref: 10221**

The Rembrandt Hotel
11 Thurloe Place
London SW7 2RS
Tel: +44 (0)20 7589 8100

Programme schedule

Registration and refreshments: 09.00
Drinks reception day one: 17.00 - 18.00

	Day one	Day two
Start	09.30	09.00
Close	17.00	16.30

Accommodation

We have arranged a preferential rate for accommodation at the venue. To take advantage of this please contact the hotel on the email below and state you are a Management Forum delegate. There are limited rooms available at this rate so please book early to avoid disappointment.

Email: reservations_rembrandt@sarova.co.uk
Web: www.sarova-rembrandthotel.com

For information on alternative accommodation please visit our website: **management-forum.co.uk/accommodation**

Three ways to book

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FEE: The fee includes all meals and refreshments for the duration of the course and a complete set of course materials. If you have any particular requirements please advise customer services when booking.

PLEASE NOTE: Management Forum Ltd reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled Management Forum will refund the registration fee and disclaim any further liability.

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Book Before 20 September 2018 and SAVE £200 / €280

Now in its 9th successful year

MANAGEMENT forum

Annual Conference

A Regulatory Update on Animal Feed and Feed Additives in the EU, USA and China

Including an update on the implications of BREXIT

6-7 December 2018 London

Programme to include:

- "REFIT" of EU Regulation (EC) N° 1831/2003 on feed additives
- The changing face of EFSA - engaging stakeholders, status of new EFSA guidance
- Re-evaluation of EU feed additives – challenges remaining after seven years
- EU ten-year renewals - a smaller hurdle for approved feed additives?
- EU procedures and timelines in relation to feed additive applications
- New approaches to the risk assessment of feed additives of botanical origin
- Permitted claims and borderlines between feeds, veterinary medicines and feed additives - differences between the EU, USA and China
- US FDA approaches to the regulation of nutritional products for animals
- The legal framework for feed additives in China

To be chaired by:

Dr Elinor McCartney, President, Pen & Tec Consulting Group, Spain

With an international panel of experts:

Dr Francisco Javier Piquer, Head of Animal Nutrition, General Directorate Agricultural Products & Markets, Spanish Ministry of Agriculture, Fisheries, Food & the Environment, (MAPAMA), Spain
Ruud Bremmers, Regal BV, The Netherlands
Dr Eliana Henriquez Rodriguez, Pen & Tec Consulting, Spain
Dr Marta Ponghellini, Veterinary & International Affairs, Unit G1, Animal Nutrition, DG Health and Consumers, EU Commission
Paola Manini, Senior Scientific Officer, FEED Unit/ Scientific Evaluation of Regulated Products Directorate, European Food Safety Authority (EFSA)
Raymond Ng, China Regulatory & Market Access Manager, Precise Global, China
Dr Kristi Smedley Vice President, Center for Regulatory Services, USA
Hector Velasque-Estay, Managing Director, Pen & Tec Consulting Group, Spain

Maximise your networking by attending the drinks reception

CPD CERTIFIED The CPD Certification Service

A Regulatory Update on Animal Feed and Feed Additives in the EU, USA and China
6-7 December 2018, London

Programme

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, examine procedures and data requirements, and discuss to what extent EFSA-compliant data can be used to achieve approvals in China and the USA (or vice versa).

Where the industry is today

The EU has transformed its food legislation in the last two decades, 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, feed hygiene condition enhancers. 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 has prohibited 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 all 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 AAFCO Official Publication. The FDA now encourages sponsors to use the food additive petition procedure for new products.

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 regulatory problems.

Who should attend

- Regulatory
- Business development
- Feed business operators
- Strategic marketing managers
- Registration managers
- Product managers
- R&D scientists
- Project managers
- Senior managers seeking a "snapshot" of current regulatory trends and challenges in feeds and feed additives in Europe, China and the USA.

To be chaired by

Dr Elinor McCartney, President, Pen & Tec Consulting Group, Spain

Expert faculty

Dr Francisco Javier Piquer, Head of Animal Nutrition, General Directorate Agricultural Products & Markets, Spanish Ministry of Agriculture, Fisheries, Food & the Environment, (MAPAMA), Spain
Ruud Bremmers, Regal BV, The Netherlands
Dr Eliana Henriquez Rodriguez, Pen & Tec Consulting, Spain
Dr Marta Ponghellini, Veterinary & International Affairs, Unit G1, Animal Nutrition, DG Health and Consumers, EU Commission
Paola Manini, Senior Scientific Officer, FEED Unit/ Scientific Evaluation of Regulated Products Directorate, European Food Safety Authority (EFSA)
Raymond Ng, China Regulatory & Market Access Manager, Precise Global, China
Dr Kristi Smedley, Vice President, Center for Regulatory Services, USA
Hector Velasque-Estay, Managing Director, Pen & Tec Consulting Group, Spain

Day one — 6 December 2018

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

09.45 ▶ **Implementation of Regulation (EC) Nº 1831/2003 on Additives for Use in Animal Nutrition - An update**
- Re-evaluation of existing feed additives: where are we?
- Recent developments / ongoing discussions

Dr Francisco Javier Piquer, MAPAMA

11.00 ▶ **Discussion**

11.15 ▶ **Refreshments**

11.45 ▶ **The Role of the EU and Comitology**
- Scope of EU feed additive legislation - in or out of scope?
- Differences between feeds, feed additives and veterinary products
- Feed and feed additive claims - best practices
- Post-EFSA opinion - Comitology
- Special case of supplementary dossiers

Dr Marta Ponghellini, EU Commission

12.45 ▶ **Discussion**

13.00 ▶ **Lunch**

14.00 ▶ **New approaches to the risk assessment of feed additives of botanical origin: How to deal with complex mixtures and their variability?**
- Whole mixture versus component - based approach: data requirement, applicability and limitations
- New concepts in mixture assessment: grouping of chemicals, dose addition, handling data gaps
- The weight of evidence approach to integrate different sources of evidence
- The margin of exposure as a tool to identify the need for refinement
- How to integrate uncertainty in risk assessment

Paola Manini, European Food Safety Authority

15.00 ▶ **Discussion**

15.10 ▶ **Refreshments**

15.30 ▶ **Workshop one: Strategic options for animal nutrition products in the EU**
Led by ***Ruud Bremmers,*** Regal BV and ***Dr Eliana Henriquez Rodriguez,*** Pen & Tec Consulting

16.30 ▶ **Workshop feedback and discussion**

17.00 ▶ **Networking drinks reception**

18.00 ▶ **End of day one**

Day two — 7 December 2018

09.00 ▶ **Review of day one - Focus on EU/EFSA - BREXIT update**
Dr Elinor McCartney, *Pen & Tec Consulting*

09.15 ▶ **BREXIT Blues - Food chain blocked, broken or better?**
- Background
- Where are we now?
- Possible scenarios: best, most likely & worst case
- Consequences for UK companies in the EU
- Consequences for non-UK companies in the UK

Hector Velasque-Estay, Pen & Tec Consulting

10.00 ▶ **Study design and statistics - What EFSA wants**
- Basic EFSA-compliant study designs and key end-points
- Recent changes in statistics
- Frequently asked questions from EFSA

Dr Eliana Henriquez Rodriguez, Pen & Tec Consulting

10.45 ▶ **Refreshments**

11.00 ▶ **The US FDA approach to the regulation of feed ingredients**
- Legal and regulatory framework
- Authorisation pathways for feed ingredients
- Recent changes
- Key differences from EU

Dr Kristi Smedley, Center for Regulatory Services, USA

12.00 ▶ **The Chinese approach to feed additives**
- Regulatory management framework
- Key regulations and changes
- Import & registration procedures

Raymond Ng, Precise Global, China

12.50 ▶ **Discussion**

13.00 ▶ **Lunch**

14.00 ▶ **Workshop two: Study design and statistics**
Led by ***Dr Eliana Henriquez Rodriguez,*** Pen & Tec Consulting and ***Ruud Bremmers,*** Regal BV

14.45 ▶ **Workshop feedback and discussion**

15.00 ▶ **Refreshments**

15.15 ▶ **Workshop three: Managing dossier projects - best practices**
Led by ***Ruud Bremmers,*** *Regal BV and* ***Dr Eliana Henriquez Rodriguez,*** Pen & Tec Consulting

16.00 ▶ **Workshop feedback and discussion**

16.15 ▶ **Discussion, questions and answers**

16.30 ▶ **Close of forum**

A certificate of attendance for professional development will be available to each participant who completes the course

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