Animal NUTRA

Animal Nutrition in a Global Marketplace

Summer 2011

Volume 3

Issue 3

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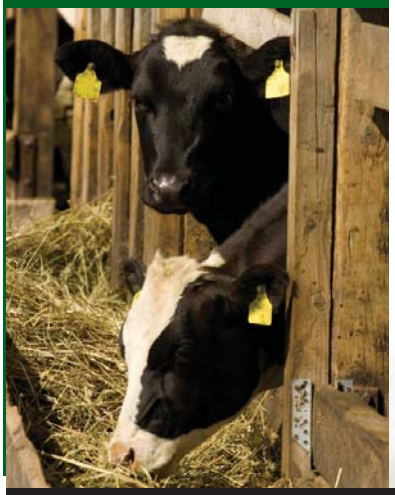

Spotlight On:

Human Exposure Assessment of Feed Additive or Veterinary Drug Residues

Overview of the Consumer Safety Assessment Process

The safety of any residues of feed additives or veterinary drugs in animal products following their use in the treatment or feeding of food producing animals, is a key consideration in the pre-market assessments of these substances. Although the specific requirements of the individual regulatory bodies may vary, the general principles behind the assessment process, as part of a pre-market authorisation, are the same. Essentially, all employ an "integrated" approach taking into account a range of factors, which ultimately lead to the determination of any necessary maximum residue limits (MRLs) or withdrawal periods (see Scheme).

The studies required for the determination of the metabolism and toxicity of the substance (or its metabolites) should be determined on a case-by-case basis. Specific activity of the drug/additive must also be taken into account where relevant, such as pharmacological effects or the potential influence of residues of antibiotic or antimicrobial agents on human gut flora. In conjunction with the metabolism of the active, actual residue data are generally obtained from deposition or depletion studies performed in the target animals. It is critical the commercial formulation of the drug or additive under the appropriate dosing/feeding regime is used in these studies. Having identified the likelihood of residues being present in edible tissues or animal products under the intended use of the veterinary drug or additive, and the hazard that these may pose, the next stage in the risk assessment process is to determine the potential consumer exposure. Conventional methods by which consumer exposure may be estimated, are summarised below.

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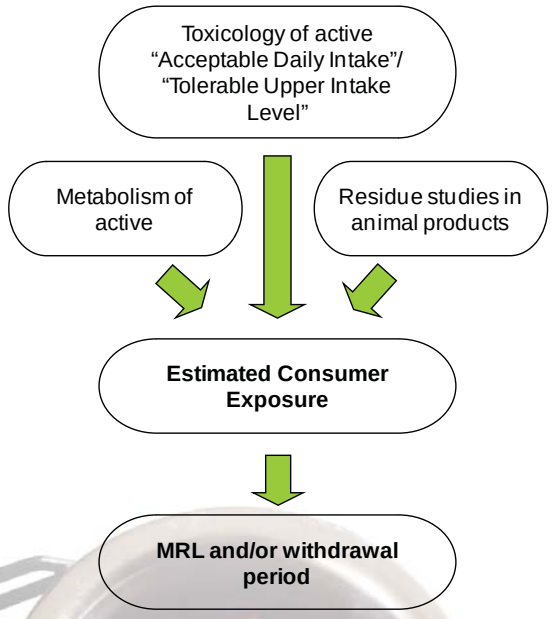
Scheme enera A roach to uman osure Assessments



Spotlight On:

Human Exposure Assessment of Feed Additive or Veterinary Drug Residues ...continued

Human Exposure Assessment

In Europe, both the Committee for Veterinary Medicinal Products (CVMP) and the European Food Safety Authority (EFSA) Panel on Additives and Products of Substances in Animal Feed (FEEDAP) utilise arbitrarily high fixed theoretical daily consumption figures for various products in the form of a "food basket" to determine conservative estimates of the intake of foods of animal origin on which to derive the MRL. The exact food basket varies with the species that might be exposed to the veterinary drug or additive but typically is determined along the lines of a person of average body weight consuming 300 g of muscle, 100 g of liver, 50 g of kidney, 50 g of fat, 100 g of eggs, 20 g of honey and 1.5 L of milk on a daily basis (as relevant to the species). Where multi-species use of the drug or additive is envisaged, theoretical daily exposure is estimated for each target animal and the highest values for each tissue are adopted for assessment purposes.

Overall, the total amount of residues present in this daily food basket is not allowed to exceed the Acceptable Daily Intake (ADI) or equivalent determined from the toxicology data. At this stage, account is also taken of the pattern of residue depletion of the substance through the target animal and the possible persistence of residues in specific organs such as the liver or kidneys. Additionally, the exposure by consumers to the ingredient from other sources (*e.g.*, both additive and veterinary drug use, background consumption from the normal diet) must be addressed. Thus, whilst the food basket methodology represents a "worst-case" scenario and is the first step or "tier" in any consumer exposure assessment, it may be appropriate in many instances to follow this with subsequent tiers of analysis, utilising more refined information that better represent intake on a practical basis. These assessments would utilise actual consumption data often collected as part of national food surveys. When utilising sample data, based on finished foods from these types of surveys, there is a need to translate back into foods as eaten. For example, it is required to convert a pepperoni pizza topping, as consumed, into the corresponding amount of raw meat, or to convert a yogurt into the original milk. Following completion of the most appropriate consumer exposure assessment, the MRL is derived such that the ADI is not exceeded. Once MRLs have been allocated, the requirements for any withdrawal period are addressed.

Another important aspect of the human exposure assessment is considering sources of residue information other than those obtained directly from the deposition/depletion studies. The value of these sources for providing more realistic or additional information on residue levels is critically dependent on the quality of the tissue/food concentration data. Analytical data on concentrations of chemicals in food may be obtained from monitoring and surveillance data. In utilising such data, it is important to be aware of the survey design, sampling procedures, sample preparation, analytical method, limit of detection and quality assurance procedures. The use of "suspect" samples for use in exposure assessment is discouraged as these data can exaggerate the actual level of contamination dramatically. Suspect samples are those taken from an animal/animal product which, based on examination prior to entry into the food chain, are suspected of non-compliance. *For more information on how our experts can assist with exposure assessments, contact us at feed@cantox.com.*

Upcoming Events

2011 AAFCO Meeting
Jul 30 - Aug 1, 2011
Austin, TX, USA
(http://www.aafco.org)

WSPA Symposium on Quality of Meat, Eggs, and Egg Products
Sept 4 - 8, 2011
Leipzig, Germany
(www.eggmeat-2011.de)

2011 AFIA Liquid Feed Symposium
Sept 13 - 15, 2011
Kansas City, MO, USA
(www.afia.org)

World Veterinary Congress
Oct 10 - 14, 2011
Cape Town,
South Africa
(www.worldvetcongress 2011.com)

18th European Symposium on Poultry Nutrition
Oct 31 - Nov 4, 2011
Çesme, Izmir, Turkey
(www.espn2011.org)

Royal Agricultural Winter Fair
Nov 4 - 13, 2011
Toronto, Ontario, Canada
(http://royalfair.org/)

Cantox plans to hold a workshop on the new GRAS notification process for feed ingredients towards the end of 2011.

To receive updates on this and any other events contact:

feed@cantox.com

Regulatory News

Europe

Sampling and Analysis of Genetically Modified Material

Commission Regulation (EU) 619/2011 laying down methods of sampling and analysis regarding the presence of genetically modified (GM) material in feeds for which authorisation is pending or expired, seeks to address discrepancies in the current treatment of these types of products across Member States. In particular, the regulation sets out a "technical zero", which is the lowest level of GM material considered by the EU Reference Laboratory (EURL) to give sufficiently reproducible results between official laboratories. The level is set at 0.1% and is referred to as the Minimum Required Performance Limit, or MRPL. Any products not meeting this limit must be declared as non-compliant by the Member States. (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:166:0009:0015:EN:PDF)

Updated Feed Materials Catalogue

Commission Regulation (EU) No 575/2011 of 16 June 2010 provides an updated Catalogue of feed materials including modifications to existing entries in addition to new entries. The list is non-exhaustive and all feed materials placed on the market for the first time should be notified by way of the feed materials register, which is solely operated by representatives of the European feed business sectors. Following publication of Regulation (EU) No 575/2011, any entries now in the Catalogue have been removed from the register. (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:159:0025:0065:en:PDF)

Consolidated Contaminant Legislation

Levels of undesirable substances in animal feed are controlled under Directive 2002/32/EC in the EU and its many ammendments. Commission Regulation (EU) No 574/2011 of 16 June 2011 includes the most recent amendments, with maximum levels set for nitrate, melamine, *Ambrosia* spp. and carry-over of certain coccidiostats and histomonostats. Furthermore, the regulation provides consolidated Annexes listing maximum levels of undesirable substances and any thresholds for triggering investigative action by Member States. The annexes have been restructured to allow for the harmonisation of terminology and to improve readability. (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:159:0007:0024:EN:PDF)

United States

Generally Recognized as Safe (GRAS) Notification Program

The GRAS notification program for feed ingredients has been recently introduced by the FDA Center for Veterinary Medicine (CVM). As part of the program, the Animal Food GRAS Notices Inventory has now been launched by the FDA CVM listing all substances notified to date. The FDA CVM, requires the same quality of data for a GRAS determination as a food additive petition, and therefore, reviews are expected to demand comprehensive information packages and meet rigorous standards. (http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/GenerallyRecognizedasSafeGRASNotifications/ucm243845.htm)

New Regulations Under the Food Safety Modernization Act

The FDA has announced the introduction of the first two new regulations under the Food Safety Modernization Act pertaining to the prevention of the availability of potentially unsafe food and feed products in the US. The first regulation provides the FDA with greater authority to detain for up to 30 days food or feed products believed to have been produced under unsafe or unsanitary conditions. During the detention period, the FDA will determine whether to allow the marketing of the product. Under the second regulation, anyone importing food or feed products into the US is required to inform the FDA if the product has been refused entry by any other country. Both rules became effective July 3, 2011. (http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm253983.htm)

Canada

CFIA to Amend the Feeds Regulations

The Canadian Food Inspection Agency (CFIA) is preparing to update Schedules IV and V (*i.e.*, lists of ingredients approved for manufacture, import, and sale for use in livestock feed) of the Canadian Feeds Regulations. The proposed changes include the addition of newly approved ingredients and approved changes to existing ingredients Additionally, it is proposed that the Regulations be amended to shorten the period of time between the CFIA's approval of a new ingredient and its incorporation into Schedule IV or V, enabling quicker marketplace availability. (http://www.inspection.gc.ca/english/anima/feebet/ind/schedu4e.shtml)

In Profile with...

Áine Hearty, Ph.D

Scientific and Regulatory Consultant
Cantox Health Sciences International

Dr. Áine Hearty is the most recent addition to the Food and Nutrition Group at Cantox Health Sciences International, an Intertek company (Intertek Cantox). As Intertek Cantox's Senior Intakes Specialist, Dr. Hearty brings extensive experience and strong technical knowledge in modeling dietary intake data for the estimation of human exposure to chemicals including food/feed additives, flavourings, food contact material migrants, and nutrients.

Dr. Hearty was recruited to participate in the EFSA Food Additive and Nutrient Sources, and the Food Consumption and Exposure Assessment working groups, where she made significant contributions to developments in this area. Dr. Hearty held the position of Project Manager on an European Union (EU) 7th-Framework funded project assessing exposure to flavourings, additives, and food contact materials. Prior to this, she was a Senior Research Nutritionist for the Irish Universities Nutrition Alliance, where she was involved in both EU-funded and nationally-funded projects related to dietary intakes and food chemical exposure assessments.

With the addition of Dr. Hearty to our strong scientific team in the Food and Nutrition Group, Intertek Cantox expands its scope of consulting services and its capacity to deliver technical expertise to develop and manage global food and feed intake programs using international nutrition surveys and to implement alternate methods of analysing dietary intake data. As part of this work, Dr. Hearty is well placed to advise on, and to conduct, consumer exposure assessments relating to feed additive or veterinary drug residues.

Did you know…

Cantox has over 25 years of experience in the preparation of professional and high-quality safety assessments, including:

- **Feed GRAS dossiers for the US market,**
- **Feed additive dossiers for the European market,**
- **And feed safety assessments for many more international markets!**

Contact Cantox
for all of your feed safety needs!

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Animal Nutra is a periodic newsletter published by Cantox Health Sciences International, an Intertek company (Intertek Cantox) for the purpose of keeping our clients and other interested parties informed of brief reviews of regulatory updates, and exciting events of interest to the global market for veterinary feeds and nutraceuticals. Email us with your new research, upcoming events and business items at feed@cantox.com.

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