CONFERENCE/WORKSHOP ORGANISER'S REPORT

"SASKVAL III - Saskatoon International Workshop on Validation and Regulatory Analysis"

The opinions expressed and arguments employed in this report are the sole responsibility of the authors and do not necessarily reflect those of the OECD or of the governments of its Member countries.

Brief Description of what the conference/workshop was about

The Workshop was organized to assemble together experts from the research community and those in the non-scientific policy-forming sector involved in the primary production of agri-food and aquaculture products for which veterinary drugs are used. The goal was to provide a forum for the two groups to gain a better understanding of the underlying issues related to the practice of using these drugs in food animal production and how they impact both the human health safety issues and global trade with the expectation that this would enable the development of a sound knowledge base for making sound risk assessment and risk management decisions. In addition, it was expected that the Workshop would provide the required forum to assist and inform the public debate on current and emerging challenges facing the agri-food industry to help increase face-to-face public debate/discussion between the scientists in the analytical community and experts involved in policy decision making. In that regard, the Workshop was designed to centre around 7 themes.

Participation – details of total number of participants, countries they came from, backgrounds (academia, industry, etc.)

A total of 76 participants attended the Workshop held in Calgary, Alberta, Canada. They were from Canada (39), USA (14), Belgium (4), Qatar (3), France (3), 2 each from The Netherlands, Portugal, United Kingdom, Ireland, and one each from the Kingdom of Saudi Arabia, Republic of Korea, Switzerland, Israel and Hong Kong, Of these, 33 were from government, 15 were from academia, 17 were instrument and equipment manufacturers and primary producers, 10 from industry and 1 was a retired government official. While the greater majority of participants were involved in generating the database for risk analysis and risk assessment for the veterinary drugs of interest to this community, there was a sizeable number of participants who were risk managers directly involved in making risk policy and risk management decisions.

Major highlights from the presentations

Theme 1 - Codex Alimentarius Commission Decisions of Interest to the Analytical Community: The production of medicated feed at the farm and the production facilities; carry-over between medicated feed and non-medicated feed produced in the same production facility leading to cross contamination and inadvertent production of feeds with low levels of antimicrobials; the possibility of the contaminated feed containing low levels of antimicrobials contributing to generation of antimicrobial resistance. There was also a perception that there were significant gaps in the setting of standards and development of methods for residues in honey.

Theme 2 - Chemical Residue and Contaminant Testing; Emerging and Alternate Technologies: Biomarkers are considered interesting tools for drug identification and speciation (omic research) and uncovering fraudulent labelling practices. Very often, as soon as these biomarkers are known, they become "normal targeted analytes and the question arose as to how these can be used in regulatory control programs? Will their use stand the scrutiny of legal action? In the same session, it was remarked that because the sensitivity of our analytical methods are constantly increasing, it is becoming more and more difficult now to differentiate between compounds which were at one time considered to be exogenous but are now considered to be endogenous. There is currently no concentration threshold that distinguishes an endogenous compound from an exogenous one.

Theme 3 - High Throughput Analysis in Labs and Food Production: There was unanimous agreement that most of the guidance documents currently recommended for use in residue laboratories by the European Commission and the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) related to confirmatory analysis need to be extensively revised to take into consideration new scientific data that have been reported in many scientific publications in the last decade. In addition, the revisions must include the use of high resolution mass spectrometers (HRMS) in the routine regulatory analytical methods based on current available science.

Theme 4 - International Harmonization of Analytical Methods and Processes: While the Regulatory Communities may be reactive when it comes to focussing on current issues like food hygiene, drug residues and antimicrobial resistance, they must also be proactive in predicting the risks in food safety for tomorrow. Risk based analysis must become the basic principle upon which analytical methods are applied in the community. New strategies must be developed to detect risks at an early stage to improve the risk analysis process.

Theme 5 – Sports Doping: First Past the Post before Veterinary Drug Abuse? Show Cows and Race Horses: The session discussed medication use and abuse in equine performance in show jumping and chuck wagon racing and considered the difficulties associated with tracking such horses once they were out of the racing cycle and the concern that these may be introduced into the food chain. The session also noted that because plants fed to horses including hay, grass are rich with phytosterols, it is sometimes impossible to accurately determine whether the presence of steroids such as β-boldenone detected in some race horses, were endogenous resulting from feeding practice or present as a result of a treatment regimen. In that same session, efforts to monitor the use of veterinary drugs in aquaculture and their environmental effects on coastal vegetation were presented.

Theme 6 – Antibiotics in the Environment, Food Chain, Aquatic and Food Animal Production: Is There a Link to Antibiotic Resistance? There was agreement that studies show a link between antibiotic use in animals and increased antimicrobial resistance in humans; there were noted differences between countries in terms of the availability and access to veterinary drugs and it would be good if regulatory authorities learned from one another.

Theme 7 – Pharmacokinetics and Depletion Studies: This session looked at the regulatory guidelines and their application to the residue and pharmacokinetic studies and how these are used by expert bodies such as the Joint WHO/FAO expert Committee on Food Additives (JECFA) to establish internationally acceptable safe limits for the use of approved veterinary drugs.

Major outcomes/conclusions in terms of policy relevance

Theme 1: There was a recommendation to establish an electronic working group to assess the problems, evaluate significance, raise awareness and inform and provide support to the risk management process. Another recommendation was to establish a second working group to prepare a summary document that provides an overview of the work that has been done or is ongoing for honey for distribution to the participants and to CCRVDF. The terms of reference of these working groups will be established before the end of 2015.

Theme 2: Develop more discriminatory genomic techniques for the classification of endogenous versus exogenous compounds.

Theme 3: Regulatory agencies and instrument manufacturing companies must develop strategies to make the use of high resolution mass spectrometry techniques routine in regulatory monitoring programmes.

Theme 4: Risk-based approaches must be universally implemented in residue monitoring programmes in the near future.

Theme 5: There is a need to create a rational detection time in order to reduce drug abuse in the equine racing industry, while still allowing for therapeutic medication.

Theme 6: It would be important for these working group to play a key role in educating the public regarding the issues and risks associated with antimicrobial resistance; continue to improve residue monitoring control

programmes; develop more effective formulations as far as drug bioavailability is concerned; include antimicrobial resistance issues and expertise as part of the working group (session 1) looking at cross contamination of medicated feeds.
Theme 7: Methods used to study the pharmacokinetics and/or depletion of veterinary drugs in food animals must meet the requirements of Good Laboratory Practice (GLP) and/or be adequately validated according to international guidelines such as the ISO/IEC 17025:2005, CAC/GL 71-2009. The methods must be used in an accredited facility.

Relevance to CRP theme(s)
The feedback provided by workshop attendees clearly indicated that the workshop had:

- succeeded in developing a sound knowledge base for agricultural policy making;
- considered and developed strategies that would help to ensure that our food is safe to eat today and tomorrow;
- provided a forum to assist and inform the public debate on current and emerging agri-food and agri environmental matters,
- acknowledged that the funding provided by the OECD CRP enabled us to promote international scientific understanding among OECD member countries and non-OECD member countries with respect to efforts to provide sustainable agriculture and aquaculture for tomorrow's world.
- given the participants a platform to continue, even after the workshop, to inform public debate and discussion on the issues of carry-over contamination as well as efforts to classify endogenous and exogenous substances in foods.

Website for further details – please also indicate if the presentations are/will be available on the website
The Workshop presentations will be available soon at: http://www.saskval.com
In addition, a special publication of the proceedings of the Workshop will be published soon in a peer-reviewed journal, Drug Testing and Analysis.