SASKATOON INTERNATIONAL WORKSHOP
VALIDATION AND REGULATORY ANALYSIS

Atelier International de Saskatoon
Validation et analyse de réglementation

SUMMARY OF THE SASKVAL II INTERNATIONAL WORKSHOP ON VALIDATION AND REGULATORY ANALYSIS HELD IN SASKATOON, SASKATCHEWAN, CANADA, JUNE 19-22, 2011.

The Workshop was organized to provide a forum for reviewing current and emerging analytical methods used in regulatory laboratories to support programmes ensuring that veterinary drugs and feed additives used in food animal production (from the live animal on the farm to slaughter) and honey are used properly; that the methods that are being used to support the production of safe food are fit-for-purpose and meet current domestic and international regulatory requirements to facilitate trade on the global market; and that the analytical methods are being used to generate data that could be used in making assessment decisions that can be used by risk managers to make informed decisions.

The SASKVAL II Workshop was sponsored in part by the OECD Co-operative Research Programme on Biological Resource Management for Sustainable Agriculture Systems. This financial support made it possible for some of the invited speakers to attend and participate in the Workshop.

The opinions expressed and arguments employed in this report, however, are the sole responsibility of the organizing committee of the SASKVAL II Workshop and do not necessarily reflect those of the OECD or of the governments of its Member countries.

SASKVAL II was held in Saskatoon June 19 – 22, 2011 at the Sheraton Hotel and was opened on Monday, June 20th by Dr. Keith Campbell, Executive Director, Western Laboratory Network of the Canadian Food Inspection Agency (CFIA), substituting for Dr. Martine Dubuc, Vice President, Science Branch, CFIA.

This is the only international meeting on validation and regulatory analysis held in North America. The Workshop was held for the first time in the same city in June 2007 and one hundred and five participants from 28 countries attended the Workshop.

SASKVAL II attracted participants from Canada, Israel, Slovenia, Hong Kong, Argentina, Republic of Korea, New Zealand, USA, Republic of Chile, Brazil, Ireland, Sudan, United Kingdom, Georgia, France, Italy, Estonia, Austria, Switzerland, Malaysia, Sweden, The Netherlands, India, Republic of Uruguay, Germany, South Africa and Belgium.

The first day session covered aspects of residue control program design and quality management systems. A special symposium was held that evening to discuss the Codex Draft Guideline Document "Development of performance criteria for multi-residue analytical methods for regulatory control" which was being prepared for Codex Committee for Residues of veterinary Drugs in Foods (CCRVDF) under the joint co-chairmanship of Canada (Boison) and the UK (Kay). An opportunity was provided for those who did not want to attend the Symposium to visit the Canadian Light Source (Synchrotron Radiation Centre) at the University of Saskatchewan.

The second day session covered current analytical methods and emerging technologies used to support residue control programs to ensure food safety.

The third day sessions covered risk management issues associated with the maintenance of residue control programmes and considered options available for bringing risk managers and risk managers/regulators together to make informed decisions.

While it wasn't the initial intention of the Workshop organisers, it turned out that the technical sessions had been arranged in such a way that the Workshop was able to nicely tie together risk assessment and risk management activities.

In conclusion, Dr. Primal Silva, Executive Director, Animal Health Science Directorate, CFIA, and Member of the Scientific Advisory Board of the Organization for Economic Co-operation and Development (OECD), observed that the Workshop had provided the participants with a forum to discuss how to improve science through improved analytical methods and doing more with less. It had also provided a key opportunity for delegates to feed into discussions on evolving CODEX documents to improve clarity and applicability for the current scientific environment, noting that it is through these sound documents that sound policies can be made. The meeting also highlighted the need for working together to improve food safety through improved communication between all parties involved in the process. He observed that even though it wasn't discussed at this workshop, food security is also of growing importance. Food abundance and transportation issues are becoming significant issues internationally. To address this, nations need to come to agreements and harmonize their regulations. Over time, we can then know how to move forward into the future to ensure sustainable agriculture.

Exit evaluation forms completed by participants indicated that the Workshop had been very successful and had met and/or exceeded expectations.

Therefore, it was unanimously recommended by the attendees and approved by the Executive and Scientific Committees for SASKVAL II to consider making plans to organize another SASKVAL Workshop in Canada in 2015 in a location (Calgary or Halifax) to be named at a later date. With this recommendation, it is very likely that the Scientific Committee for SASKVAL III will be communicating with the OECD for funding assistance in 2014.

DELIVERED OUTCOMES OF THE 2011 SASKVAL II WORKSHOP

1. A 142 page Proceedings of the SASKVAL II Workshop has been published in the Journal – Drug Testing and Analysis Volume 4 Supplement 1, 2012 – that included presentations from all the OECD funded invited and Keynote Speakers. The Website for the Journal is: www.drugtestinganalysis.com

2. The recommendations made by participants of the special symposium to discuss the Codex Draft Guideline Document "Performance criteria for multi-residue analytical methods for veterinary drugs" which was being prepared for Codex under the joint co-chairmanship of Canada (Joe Boison) and the UK (Jack Kay) were submitted to the electronic Working Group for the 21st Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) at its meeting in Minneapolis, Minnesota August 24-30, 2013). The 21st CCRVDF accepted the recommendations and advanced the recommendations to Step 8 of the Codex Standard approval process and recommended it for adoption as Annex 1 to the previously published Codex standard CAC/GL 71-2009.

3. As a result of the recommendations made in the Guidance document, United Kingdom's Veterinary Medicines Directorate (VMD) has funded a significant study to provide additional data to assist with the qualitative identification criteria for multi-residue methods for veterinary drugs. The study is involving many laboratories around the world and the current criteria are based on identification criteria extrapolated from single analyte methods previously agreed by the CCRVDF.

Quick Reference Guide to articles in "Drug testing and Analysis Volume 4, Supplement 1, August 2012. Proceedings Saskval 2011: Guest editors Christine Akre & Joe Boison

Policy articles:

- EU sampling strategies for the detection of veterinary drug residues in aquaculture species: Are they working?
- Guidelines for the validation of qualitative multi-residue methods used to detect pesticides in food

- Analytical difficulties facing today's regulatory laboratories: issues in method validation.
- Combining ISO/IEC 17025:2005 and European Commission Decision 2002/657 audit requirements: A practical way forward.
- Risk assessment and risk management at the Canadian Food Inspection Agency (CFIA): A perspective on the monitoring of foods for chemical residues.
- Metabolomics in food analysis: application to the control of forbidden substances.
- The physiological way: monitoring RNA expression changes as new approach to combat illegal growth promoter application.

Review

- The role of pharmacokinetics in veterinary drug residues.
- A review of the analytical strategies for the detection of endogenous steroid abuse in food production.

Research Articles:

- Application of EU guidelines for the validation of screening methods for veterinary drugs.
- Development and validation of a streamlined method designed to detect residues of 62 veterinary drugs in bovine kidney using ultra-high performance liquid chromatography-tandem mass spectrometry.
- The challenges of developing a generic extraction procedure to analyze multi-class veterinary drug residues in milk and honey using ultra-high pressure liquid chromatography quadrupole time of flight mass spectrometry
- Determination of hexaconozale in field samples of an oil palm plantation.
- Investigation into the experimental protocols required to determine maximum residue limits in honey
- Monitoring of florfenicol residues in fish muscle by HPLC/UV with confirmation by LC-MS/MS
- Validation of a new screening, determinative and confirmatory multi-residue method for nitroimidazoles and their hydroxyl metabolites in turkey muscle tissues by liquid chromatography-tandem mass spectrometry.

FINAL PROGRAMME OF EVENTS

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DAY 1 – Monday, June 20th 2011	
7:00 – 8:00	**Registration, Poster Set-up and Breakfast**
8:05 – 8:40	**Welcome, Housekeeping and Opening Remarks by Dr. Keith Campbell (Executive Director, Western Area Laboratories, CFIA)**
8:40 – 9:00	**OECD SAB Presentation Dr. Primal Silva)**
9:05 - 9:50	**Theme I: PROGRAMME DESIGN/QUALITY MANAGEMENT – CHAIRS: Dr. Jack Kay and Dr. Jim MacNeil** **Keynote Speaker – Prof. George Gettinby [University of Strathclyde, UK]** Quality and Fitness for Purpose of monitoring and sampling for the detection of veterinary drug residues in aquaculture species
9:50 – 10:10	EU analytical QC for pesticide residues – Mr. Stewart Reynolds (FERA, UK)
10:10 –10:25	**HEALTH BREAK**
10:30 –10:50	Combining ISO 17025 and European Commission decision 2002/657 audit requirements: a practical way forward– Dr. Jack Kay (University of Strathclyde, UK)
10:50 –11:10	Analytical difficulties facing today's regulatory laboratories – Dr. Jim MacNeil (St. Mary's University, Canada)
11:10 –11:30	Regulatory testing in the private sector - Mr. John Points (LGC, UK)
11:30 –11:50	EU criteria for veterinary drug screening methods – Dr. Linda Stolker (RIKILT – Wangeningen University and Research Centre, The Netherlands)
11:50 –12:10	Pharmacokinetics/pharmacodynamics - their role in veterinary drug residues – Prof. Peter Lees (The Royal Veterinary CollegeUK)
12:15 –13:15	**LUNCH**
13:15 –14:00	**THEME II: MULTI-RESIDUE METHODS OF ANALYSIS & VALIDATION** **CHAIR: Dr. Stefan Soback** **Keynote Speaker – Dr. Marilyn Schneider [USDA-ARS-ERRC, USA] –** Goldilocks and the 6 bears: Quest for the "just right" method for multiclass, multiresidue analysis of veterinary drug residues in food animal testing
14:00 –14:20	Matrix effects and their role in regulatory analytical methods – Dr. Joe Boison (CFIA, Canada)
14:20 –14:40	Beta-agonists LC-MS/MS analysis of bovine urine with MIPS SPE cartridges – Mr. Masahiro Mizuno (CFIA, Canada)
14:40 –14:55	The challenges of developing a generic extraction procedure to analyse multi-class veterinary drugs in milk and honey using Ultra-high pressure liquid chromatography quadrupole time-of-flight mass spectrometry – Dr. Jian Wang (CFIA, Canada)
14:55 –15:10	**HEALTH BREAK**
15:10 –17:00	**POSTER PRESENTATION (15:10 – 16:10: Presenters for odd numbered posters present; 16:10-17:00- Presenters for even numbered posters present)** **CHAIR: DR. Rick Fedeniuk**
18:00 – 20:00	**Panel/Stakeholder Meeting to discuss CCRVDF Guidance Document on Performance Characteristics for Multi-Residue Methods being developed as an Appendix to the Codex Guidance Document CAC/GL 71-2009.** **(PRE REGISTRATION REQUIRED – MEAL PROVIDED AT 5:30)**

DAY 2 – Tuesday, June 21st 2011	
8:00 – 8:30	**Breakfast**
8:30 – 8:40	**Housekeeping**
8:45 – 9:30	**THEME III: CURRENT INTERNATIONAL (GLOBAL) INITIATIVES** **CHAIR: Mrs. Valerie Reeves** **Keynote Speaker – Dr. Mark Coleman [Elanco, ELI LILY, USA] –** Elanco AOAC Global Method Modernization Project
9:30 – 9:50	IAEA/FAO initiatives for developing countries – Dr. Britt Maestroni (FAO/IAEA, Austria)
9:50 – 10:10	How to validate analytical methods for veterinary drug residue control? Toward an internationally recognised format. A view with particular consideration to LC-MS technologies – Dr. Eric Verdon (AFSSA, France)
10:10 – 10:25	**HEALTH BREAK**
10:30 – 10:50	**THEME III continued** **CHAIR: Dr. Christine Akre** A Review of Analytical Strategies for the Detection Of 'Endogenous' Steroid Abuse in Food Production– Dr. James Scarth (HFL Ltd., UK)
10:50 – 11:10	Best practices for single laboratory validation (SLV) of chemical methods for trace elements in food – Mr. Cory Murphy (CFIA, Canada)
11:10 – 11:30	Risk Management of imported foods: Comparative international approaches – Dr. Kenneth J. Rosnack (Waters Corp.,USA)
11:30 – 11:50	Validation of an analytical method for the determination of tilmicosin in whole chicken egg by LC-MS/MS – Dr. Thomas Burnett (Elanco, USA)
11:50 – 12:10	Unravelling the semi-endogenous status of thiouracil – Dr. Julie Vanden Bussche (University of Ghent, Belgium)
12:15 – 13:15	**LUNCH**
	THEME II: MULTI-RESIDUE METHODS OF ANALYSIS & VALIDATION continued **CHAIR: Mr. Bryn Shurmer**
13:15 – 13:35	Investigation into the experimental protocols required to determine maximum residue limits (MRLs) in honey – Mr. Richard Fussell (FERA, UK)
13:35 – 14:00	Trap or TOF? Practical aspects of high resolution mass spectrometry – Mr. John Points (LGC, UK)
14:00 – 14:20	Large Injection volumes and online pre-concentration for the analysis of pesticides in beverage utilizing high resolution accurate mass LCMS – Dr. Jim Kapron (ThermoFisher Scientific, Canada)
14:20 – 14:40	Determining the suitability of Premitest and KIS for screening of tetracycline residues in slaughter animals – Dr. Mariel Pikkemaat (RIKILT – Institute for Food Safety, The Netherlands)
14:40 – 14:55	Multiresidue HPLC-MS/MS determination of antibiotic residues in milk and meat for Latin American National residue programs. Prof. Osvaldo Rampoldi (Dirección de Laboratorio Veterinarios, Uruguay)
14:55 – 15:10	**HEALTH BREAK**
15:10 – 17:00	**POSTER PRESENTATION (15:10 – 16:10: Presenters for even numbered posters present; 16:10-17:00- Presenters for odd numbered posters present)** **CHAIR: DR. Les Dickson**
18:00 – 22:30	**WORKSHOP BANQUET at the Western Development Museum**

DAY 3 – Wednesday, June 22nd 2011	
8:00 – 8:30	**Breakfast**
8:30 – 8:40	**Housekeeping**
8:45 - 9:30	**THEME IV: NOVEL APPLICATIONS OF MASS SPECTROMETRY IN RESIDUE CONTROL** **CHAIR: Dr. Leen van Ginkel** **Keynote Speaker – Prof. Bruno le Bizec [LABERCA, FRANCE] –** Metabolomics In Food Analysis: Application To The Control Of Forbidden Substances
9:30 – 9:50	mRNA transcriptomics and the needed biostatistics, recent experiences with NGS (next generation sequencing) and microRNA quantification- Dr. Irmgard Reidmaier (Technical University Munich, Germany)
9:50 – 10:10	Options to detect recombinant growth hormone misuse in breeding animals – Dr. Gaud Pinel (ONIRIS, France)
10:10 – 10:25	**HEALTH BREAK**
10:30 – 10:50	**THEME IV continued** **CHAIR: Dr. Jian Wang** Targeted and Non-Targeted Pesticide Analysis using Liquid Chromatography-Quadrupole/Linear Ion Trap and High Resolution Orbitrap Mass Spectrometry – Dr. Kai Zhang (FDA, USA)
10:50 – 11:10	Aptamer technology – an emerging class of recognition molecules to rival antibodies with application to residue diagnostics in food– Ms. Sara Stead (FERA, UK)
11:10 – 11:30	Determination of the performance characteristics of a multi-residue method for nitroimidazoles and their hydroxy-metabolites in animal tissue by LC-tandem mass spectrometry. – Ms. Johanna Matus (CFIA, Canada)
11:30 – 11:50	The determination of 155 pesticide residues in grains using ultra-high performance liquid chromatography tandem mass spectrometry and ultra-high pressure liquid chromatography quadrupole time-of-flight mass spectrometry – Mr. Willis Chow (CFIA, Canada)
11:50 – 13:15	**LUNCH [Poster take-down]**
13:15 – 14:00	**THEME V: RISK ASSESSMENT/RISK MANAGEMENT FOR RESIDUE PROGRAMS** **CHAIR: Dr. Britt Maestroni** **Keynote Speaker: - Dr. Bob Dickey [FDA, USA] –** Harmful algal species and their toxins in food-detection methods, risk assessment and risk management
14:00 – 14:20	Risk-based prioritization for animal drug residue programs – Dr. Barry Hooberman (CVM/FDA, USA)
14:20 – 14:40	CFIA's risk assessment risk management program for residues – Henri Bietlot (CFIA, Canada)
14:40 – 15:00	**HEALTH BREAK**
15:00 – 17:00	**ROUND TABLE DISCUSSION** **CHAIR: Dr. Joe Boison & Dr. Jack Kay**
17:00 – 17:15	**WRAP UP & CLOSING REMARKS**
17:15 – 17:30	**OECD SAB's CLOSING REMARKS**