# AOAC VDR Sub-Group Community Meeting

**Tuesday, September 10, 2019**

**6:15 pm – 7:45 pm**

**Room : Governor's Square 11**

**Sheraton Denver Downtown Hotel**

Co-Chairs: Eric Verdon & Jian Wang

https://nacrw.org/vet-drugs


AOAC
Educate Network Collaborate
ANNUAL MEETING & EXPOSITION
133rd Annual Meeting | September 8-11, 2019 | Denver, Colorado

# ATTENDING LIST – Sign in

## VDR Sub-Group Community Meeting
## Attending List

AOAC Educate Network Collaboration
Annual Meeting & Exposition
132nd Annual Meeting • August 26–29, 2018 • Toronto, Canada

**Co-Chairs: Eric Verdon & Jian Wang**

**E-mails:** eric.verdon@anses.fr
jian.wang@inspection.gc.ca

**Website:** https://nacrw.org/vet-drugs

| Your name | Your Institute/ Company/ Laboratory | Your email | Your interest in this meeting or Comments |
|---|---|---|---|
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| | | | |

# ATTENDING LIST – Sign in

**2018 TORONTO => 2019-DENVER**

| | | | 2019-DENVER |
|---|---|---|---|
| An | Haejung | FDA-Irvine | Haejung.An@fda.hhs.gov |
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| Denney | Dan | Ataraxis | dan@ataraxisbio.com |
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| Joseph | George | Asurequality | george.joseph@asurequality.com |
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| Kaufmann | Anton | KLZH | anton.kaufmann@kl.zh.ch |
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| McGhee | Heather | Trilogy Analytical Lab | *henk@trilogylab.com ?????* |
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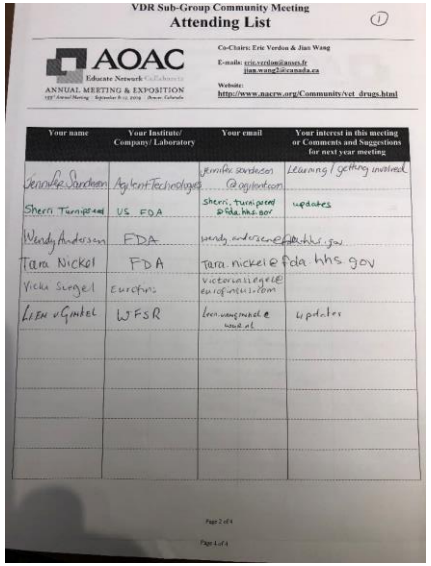
| Yang | Charles | Thermofisher | charles-young@thermofisher.com |
| Yang | Dan-Hui Dorothy | Agilent | dorothy_yang@agilent.com |
| Yeung | Jupiter | Nestlé | jupiter.yeung@rd.nestle.com |

# ATTENDING LIST – Sign in

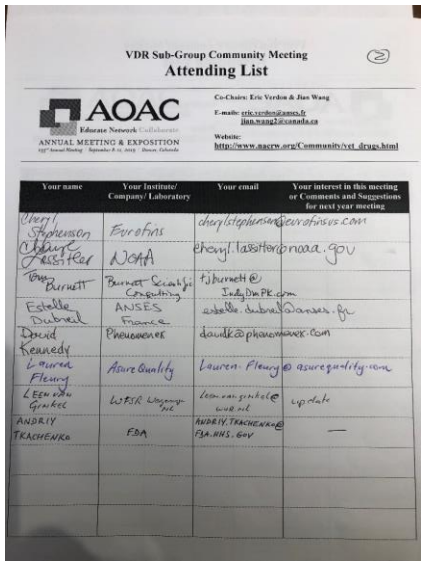
Attending List from DENVER 2019


VDR Sub-Group Community Meeting
Attending List ①

AOAC Educate Network Collaborate
ANNUAL MEETING & EXPOSITION

Co-Chairs: Eric Verdon & Jian Wang
E-mails: eric.verdon@aoaces.fr
jian.wang2@canada.ca
Website: http://www.nacrw.org/Community/vet_drugs.html

| Your name | Your Institute/ Company/ Laboratory | Your email | Your interest in this meeting or Comments and Suggestions for next year meeting |
|---|---|---|---|
| Jennifer Sanchez | Agilent Technologies | jennifer_sanchez@agilent.com | Learning / getting involved |
| Sherri Turnipseed | US FDA | sherri.turnipseed@fda.hhs.gov | updates |
| Wendy Andersen | FDA | wendy.andersen@fda.hhs.gov | |
| Tara Nickol | FDA | tara.nickel@fda.hhs.gov | |
| Vicki Siegel | Eurofins | victoriasiegel@eurofinsus.com | |
| Leen v Ginkel | WFSR | leen.vanginkel@wur.nl | updates |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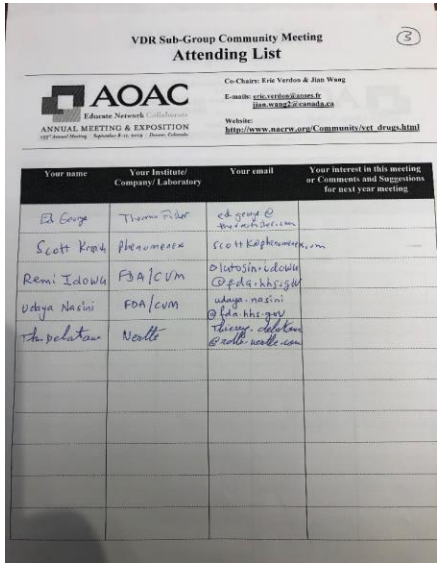
|---|---|---|---|
| Cheryl Stephenson | Eurofins | cherylstephenson@eurofinsus.com | |
| Arthur Tassitker | NOAA | cheryl.tassitker@noaa.gov | |
| Tony Burnett | Burnett Scientific Consulting | tjburnett@IndyDmPK.com | |
| Estelle Dubreil | ANSES France | estelle.dubreil@anses.fr | |
| David Kennedy | Pheuvenex | davidk@pheuvenex.com | |
| Lauren Fleury | Azure Quality | Lauren.Fleury@azurequality.com | |
| Leen van Ginkel | WFSR | leen.vanginkel@wur.nl | update |
| ANDRIY TKACHENKO | FDA | ANDRIY.TKACHENKO@FDA.HHS.GOV | — |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Website: https://www.nacrw.org/Communities/vet_drugs.html

| Your name | Your Institute/ Company/ Laboratory | Your email | Your interest in this meeting or Comments and Suggestions for next year meeting |
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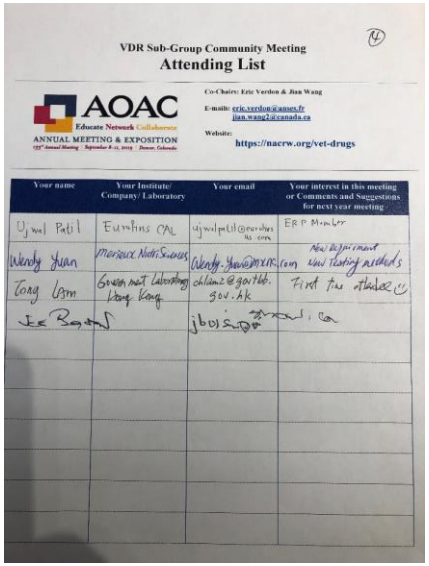
| Scott Krook | Pheuvenex | scott.krook@pheuvenex.com | |
| Remi Idowu | FDA/CVM | olutosin.idowu@fda.hhs.gov | |
| Udaya Nasini | FDA/CVM | udaya.nasini@fda.hhs.gov | |
| Thelma Dolatowski | Nestlé | thelma.dolatowski@rd.nestle.com | |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|---|---|---|---|
| Ujwal Patil | Eurofins CAL | ujwalpatil@eurofins-us.com | ERP Monitor |
| Wendy Juan | Merieux NutriSciences | Wendy.Juan@merieux-nutrisciences.com | New experiment and testing needed |
| Tong Lam | Green mat Laboratory Hong Kong | chlam2@gov.hk.gov.hk | First time attended |
| Joe Boyd | | jboyd@... | |

https://nacrw.org/vet-drugs

# Agenda

- **1. Introduction** Sub-Group Co-Chairs: **Eric Verdon and Jian Wang**

  *Sign the "sign-in sheet"*

  *to get all future subgroup updates and let us know you attended*

  https://nacrw.org/vet-drugs

- **2. Topic n°1:**

  **Latest Updates on Method Performance Criteria**

  - ***International - Pesticides*** (Jian Wang):
    - ✓ CCPR CAC/GL 90-2017 Guidelines on Performance Criteria for Methods of Analysis for the Determination of Pesticide Residues in Food and Feed
    - ✓ SANTE/11813/2017 => SANTE/?????/2019 Guidance document on analytical quality control and method validation procedures for pesticide residues and analysis in food and feed

  - ***European*** (Eric Verdon):
    - ✓ Update for Revision of European Decision 2002/657/EC on Performance Criteria for Methods of Analysis for the Determination of Vet Drug Residues in Food

# Agenda

- **3. Topic n°2:**

  Update on Multi-class Multi-residue Method on Vet Vrugs in Food Products and AOAC process to submit the proposal of method –

  by *Thierry Delatour*

- **4. Topic n°3:**

  NACRW Working Group for Veterinary Drugs

  - TO IDENTIFY CRITERIA OF PERFORMANCE FOR MULTI-RESIDUE VET DRUGS METHODS THAT WOULD MEET THE NEEDS OF GOVERNMENT REGULATORS? –

  *by Eric Verdon*

- **5. Adjournment** of Contaminant Subgroups Meeting

  for Veterinary Drug Residues

# Topic n°1

- **Latest Updates on Method Performance Criteria**

# Topic n°1

- **Latest Updates on Method Performance Criteria**

  - SANTE/11816/2017: Pesticide EU-RLs meetings will be partly dedicated for its revision or update in 2019.

  - CCPR eWG review of CXG 90-2017 and CXG 56-2005
    - CXG90-2017. Guidelines on Performance Criteria for Methods of Analysis for the Determination of Pesticide Residues in Food and Feed
    - CXG 56-2005. Guidelines on the Use of Mass Spectrometry (MS) for Identification, Confirmation and Quantitative Determination of Residues

# Topic n°1

- **Latest Updates on Method Performance Criteria**

  - CCRVDF24: JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS, Chicago, United States of America, 23–27April, 2018

    - Agenda Item 9. Discussion paper on the revision of the criteria for the use of multi residue analytical methods for the determination and identification of veterinary drugs in foods in CXG71-2009.

    - CCRVDF decided to discontinue this Agenda Item for the time being.

# Topic n°1

- **Latest Upate on Method Performance Criteria**

# Topic n°1

- **Latest Updates on Method Performance Criteria**

COMMISSION

**COMMISSION DECISION**

**of 12 August 2002**

**implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results**

*(notified under document number C(2002) 3044)*

**(Text with EEA relevance)**

(2002/657/EC)

Under REVISION 2016-2020

http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32002D0657

# Topic n°1

- **Agenda and Objectives of this Revision :**

  - ❖ To update and reorganize the currently 3 technical documents :

    => **Decision 657/2002/EC** (main piece of regulation)

    + => Doc SANCO/2726/2004 (addings)

    + => Guidance CRLs 2010 for Screening Methods

# Topic n°1

- **Agenda and Objectives of this Revision :**

  - ❖ **Confirmatory issues** : identification & quantitation

    - Criteria linked to the **Exact Mass Measurement in HRMS**
    - **Ion Ratio Tolerances** in LR-MS/MS and HR-MS/MS
    - **LC Retention Times** Tolerances
    - **CCalpha for confirmation** /
      for prohibited substances : LOD / LOQ / MMPR
      for authorized substances : MRL

# Topic n°1

- **Agenda and Objectives of this Revision :**

  - **Confirmatory issues** : identification & quantitation
    - Criteria linked to the **Exact Mass Measurement in HRMS**
    - **Ion Ratio Tolerances** in LR-MS/MS and HR-MS/MS
    - **LC Retention Times** Tolerances
    - **CCalpha for confirmation** /
      for prohibited substances : LOD / LOQ / MMPR
      for authorized substances : MRL

  - **Screening issues** : for biological and physico-chemical methods
    - Criteria for Validation on Screening in Multi-Class/Multi-Residue ($100^{+}$ analytes) by LC-MS/MS or LC-HRMS
    - HRMS data acquisition modes for screening with low FN rate
    - CCbeta for screening versus LOD
    - Methods designed for both Screening and Confirming/quantifying

# Topic n°1

- **Agenda and Objectives of this Revision :**

  **=> Currently :**

  ❖ Draft version of Updated Regulation (Summer 2019)
  named Doc/SANTE-11988-rev0
  and to be replacing the CD 2002/657

  ❖ Additional Technical Guidances

  - ➢ Recommendation for validation of **screening** methods
  - ➢ Recommendations for validation of **confirmatory** methods
  - ➢ Recommendations for the ongoing **routine control** practice
  - ➢ Recommendations for **extension** of validated methods
    - ✓ Extending analytes
    - ✓ Extending food commodities
    - ✓ Extending range of concentrations

# Topic n°2

## Update on multi-class multi-residue method on veterinary drugs in food and AOAC process to submit the proposal of analytical method

– by Thierry Delatour

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# Topic n°2

**AOAC SMPR® 2018.010**

***Standard Method Performance Requirements* (SMPRs®) for Screening and Identification Method for Regulated Veterinary Drug Residues in Food**

Intended Use: Routine Surveillance for GMP Compliance

***1 Purpose***

AOAC SMPRs describe the minimum recommended performance characteristics to be used during the evaluation of a method. The evaluation may be an on-site verification, a single-laboratory validation, or a multi-site collaborative study. SMPRs are written and adopted by AOAC stakeholder panels composed of representatives from the industry, regulatory organizations, contract laboratories, test kit manufacturers, and academic institutions. AOAC SMPRs are used by AOAC expert review panels in their evaluation of validation study data for method being considered for *Performance Tested Methods*℠ or AOAC *Official Methods of Analysis*℠, and can be used as acceptance criteria for verification at user laboratories.

***2 Applicability***

A method or a suite of methods that can screen for and identify regulated veterinary drug residues with established maximum residue limits (MRLs) in bovine milk, muscle, and fat; chicken muscle, skin with adhering fat, and eggs; and fish. Table 1 is provided

*Probability of detection (POD).*—Proportion of positive analytical outcomes for a qualitative method for a given matrix at a given analyte level or concentration. [Appendix H: *Probability of Detection (POD) as a Statistical Model for the Validation of Qualitative Methods*, *Official Methods of Analysis of AOAC INTERNATIONAL* (2019) 21st Ed., AOAC INTERNATIONAL, Rockville, MD, USA (http://www.eoma.aoac.org/app_h.pdf)]

***5 Method Performance Requirements***

*See* Table 2.

***6 System Suitability Tests and/or Analytical Quality Control***

Suitable methods will include blank check samples and check standards at 0.5x MRL prepared in matrix. Method developers will provide information on how cutoffs are determined.

***7 Reference Material(s)***

Refer to Annex F: *Development and Use of In-House Reference Materials* in Appendix F: *Guidelines for Standard Method Performance Requirements*, 21st Ed. of the *Official Methods of Analysis of AOAC INTERNATIONAL* (2019). Available at http://www.eoma.aoac.org/app_f.pdf

***8 Validation Guidance***

Appendix D: *Guidelines for Collaborative Study Procedures to Validate Characteristics of a Method of Analysis*, 21st Ed. of the *Official Methods of Analysis of AOAC INTERNATIONAL* (2019). Available at http://www.eoma.aoac.org/app_d.pdf

# Topic n°3

- **NACRW Working Group for Veterinary Drugs**

**TO IDENTIFY CRITERIA OF PERFORMANCE FOR MULTI-RESIDUE VET DRUGS METHODS THAT WOULD MEET THE NEEDS OF GOVERNMENT REGULATORS?**

# Topic n°3

- **NACRW Working Group for Veterinary Drugs**

**TO IDENTIFY CRITERIA OF PERFORMANCE FOR MULTI-RESIDUE VET DRUGS METHODS THAT WOULD MEET THE NEEDS OF GOVERNMENT REGULATORS?**

Exchange of information among scientists of regulatory labs to suggest criteria to be applied to new multi-class / multi-residue methods (100+ / 200+ substances) for screening and also possibly to confirming for veterinary drugs in food.

# Topic n°3

## AGENDA at the NACRW meeting

### Sunday July 21st 2019, Naples, FL, NACRW

2:45 - 4:15 pm NACRW Veterinary Drugs Working Group Orchid 1-2

*Identify and recommend multi-residue veterinary drug methods that will meet the needs of government regulators.*

- INTRO of the WG – OVERVIEW
- INTRODUCING THE CONCEPT & IDEAS
- HIGHLIGHTS ON EXISTING INTERNATIONAL GUIDANCES
- TRENDS IN DIFFERENT REGIONS OF THE WORLD (US, EU, CHINA)
- CRITICAL ISSUES TO DISCUSS AND TO REVIEW
- 2020 ROADMAP FOR THE WG toward a WHITE PAPER …

# Topic n°3

## HIGHLIGHTS ON EXISTING INTERNATIONAL GUIDANCES FOR VDRs

**CX/RVDF 13/21/7**

**CCRVDF ELECTRONIC WORKING GROUP ON MULTI-RESIDUE ANALYTICAL METHODS: PAPER ON REVISION OF THE DRAFT REPORT ON PERFORMANCE CRITERIA FOR MULTI-RESIDUE ANALYTICAL METHODS AND THE DEVELOPMENT OF A GENERIC VALIDATION PROTOCOL FOR THESE METHODS**

**eWG period of work : 2011-2015 led by UK & Canada**

**Recommendations:**

- The WG unanimously agreed that the revised draft Guideline be inserted as an Appendix to CAC/GL 71-2009;
- The draft Guideline should be advanced to step 5/8;

# Topic n°3

# Other international collaborative initiative for VDR MRM methods ?

Analytica Chimica Acta 962 (2017) 60–72

Contents lists available at ScienceDirect

Analytica Chimica Acta

journal homepage: www.elsevier.com/locate/aca

## A global inter-laboratory study to assess acquisition modes for multi-compound confirmatory analysis of veterinary drugs using liquid chromatography coupled to triple quadrupole, time of flight and orbitrap mass spectrometry

Bjorn J.A. Berendsen [a, *], Thijs Meijer [a], Hans G.J. Mol [a], Leen van Ginkel [a], Michel W.F. Nielen [a, b]

[a] RIKILT Wageningen University & Research, Akkermaalsbos 2, 6708WB, P.O. Box 230, 6700AE, Wageningen, The Netherlands
[b] Wageningen University & Research, Laboratory of Organic Chemistry, Stippeneng 4, 6708 WE, Wageningen, The Netherlands

# Other international collaborative initiative for VDR MRM methods ?

**AOAC SMPR® 2018.010**

***Standard Method Performance Requirements*** **(SMPRs®) for Screening and Identification Method for Regulated Veterinary Drug Residues in Food**

Intended Use: Routine Surveillance for GMP Compliance

=> Advances presented by Thierry D. just before in Topic n°2

# Topic n°3

## TRENDS IN DIFFERENT REGIONS OF THE WORLD

State-of-play in USA

(Sherri Turnipseed, US-FDA, Denver CO)

State-of-play in EU

(Eric Verdon, Anses-Fougeres France, EU-RL)

State-of-play in CHINA

(John Lee, Agilent  by Steven Lehotay)

(Dongmei Chen, HZAU, China)

# Topic n°3

## SUGGESTED CRITICAL ISSUES DISCUSSED

1 – Survey on MRM for VDR : Which Technologies suitable for Multi-Residue Methods ?

2 – Level/Quality of VDR Substances Identification ? Minimum required criteria to be applied …

3 – To Screen and to Confirm at same step of control ? Minimum criteria to be applied …

4 – Clarification of Screening versus Quantitative and Confirmatory Methods ?

5 – Alternative method validation Guidance for large multi-analyte methods ?

6 – SMPRs proposed by AOAC for vet drug screening to be applicable to regulatory monitoring ?

Need to modify POD (criteria for False Pos/Neg)?

Does not include banned residues ?

# Topic n°3

- **Next Steps :**
  - To agree upon a clear definition of what means Multi-residue/Multi-class ‘’SCREENING’’ Methods for Regulatory use
  - To agree upon the acceptable scope of instrumentation
  - To agree upon how to evaluate the acceptability of proposed methods
    - acceptable criteria
    - demonstration of performance
    - pragmatic approach by means of collaborative studies

# The 2020 ROADMAP towards a WHITE PAPER

**Who ?** Building the VDR WG : first acting circle of Reg Lab 10-12 scientists and second circle of any interested people acting their interest participating to

**When ?** Possibly 6 bimonthly Conf Calls for the 1st circle of members
=> Acting Calendar 2019-2020 to be scheduled

**Where ?** Next face-to-face meeting together with 2nd circle in July 2020

**How ?** E-mailing exchange and opening a WG access Forum

# Topic n°3

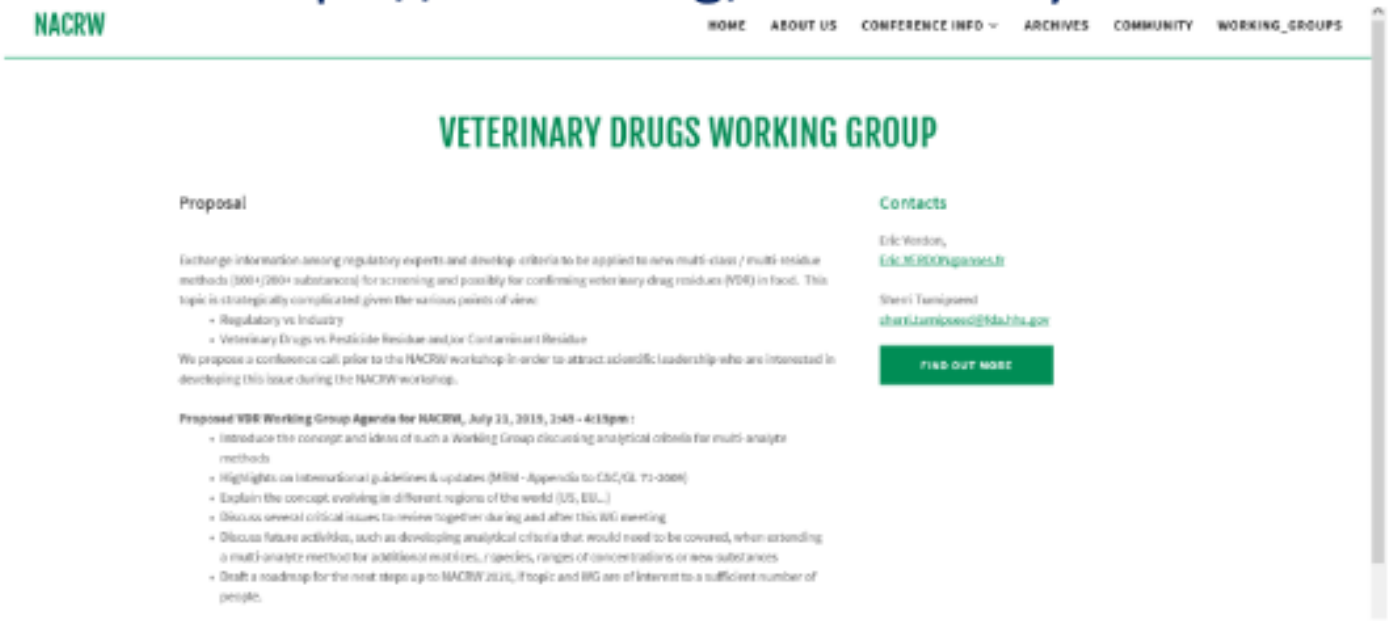
- Current Members of the 1st Circle of Reg Lab scientists :

  - from State of Florida, Dept. of Agriculture;
  - from US-FDA-ADRC-Denver;
  - from US-FDA-CFSAN-College Park;
  - from US-DA-ARS-Wyndmoor;
  - from EU-RL Anses-Fougeres for Antibiotics VDR;
  - from KLZH-Zurich-Switzerland;
  - from CFIA-Calgary-Canada;
  - from HZAU-Wuhan-China;
  - from PoloTechn-Faculdad de Quim-University of Uruguay;

  - from WFSR-Rikilt-Wageningen EU-RL for GPA-VDR ?
  - from BVL-Berlin EU-RL for Anthelmintics/Betagonists VDR ?
  - from another Asian Country ?

# Topic n°3

https://nacrw.org/community



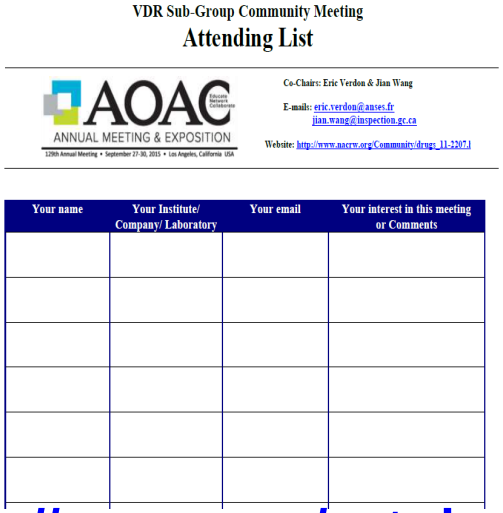

WHERE TO FIND NEWS

# AOAC VDR Sub-Group Community Meeting

- **Any Other Business or Request from the Sub-Group Attendance**


?

- **Please be sure having signed in to the attendance list to receive further information and slides**



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jian.wang@inspection.gc.ca

Website: http://www.nacrw.org/Community/drugs_11-2207.l

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|---|---|---|---|
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https://nacrw.org/vet-drugs

# Scientific sessions and Meetings of concern for the VDR sub-group

- **Monday,** September 9, 2019
  - 3:30 pm – 5:00 pm : **Symposium**: MultiClass/MultiResidue Veterinary Drug Methods – Which Strategies and for What Purpose ?
  - 5:00 pm – 7:00 pm : **Meeting** - Chemical Contaminants and Residues in Food Community Meeting

- **Tuesday**, September 10, 2019
  - 8:15 am – 9:45 am : **Symposium**: Applying Non-Target Data Acquisition for Target Analysis (nDATA)
  - 10:15 am – 11:45 am : **Symposium**: New Blood 2019 – developing methods fo rthe detection of important chemical analytes, residues & contaminants
  - 6:15 pm – 7:45 pm : **Meeting** - Contaminants Sub-group Meeting - Veterinary Drugs

- **Wednesday**, September 11, 2019
  - 8:15 am – 9:45 am : **Symposium**: Steve Moser Memorial Session
  - 10:00 am – 1:30 pm : **AOAC Expert Review Panel** for Veterinary Drug Residue Methods
  - 10:00 am – 5:00 pm : **Poster Presentations** - Analysis of Food-borne and non Food-borne Contaminants and Residues

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