

# 2014-2015 AFDO FINAL COMMITTEE REPORT

## International & Government Relations Committee

**Chair:** Robert Scales, Health Canada

**\*Chair:** Mark Roh, FDA, USA

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**Charge #1:** Identify topics of interest and international speakers for the 2015 annual conference.

**Discussion:** The Committee discussed this at length and agrees that AFDO is at a critical juncture in its 119 year history. The current global business environment requires that government regulatory bodies take a different approach to how they conduct their business of overseeing product safety and integrity in the ever changing market place. In order to stay relevant in this new environment, AFDO must expand its member activities to include foreign regulatory partners, or AFDO will become irrelevant in the global environment. Canada, Mexico and the United States of America are each other's major trading partners. AFDO must embrace the regulatory bodies of these three countries and expand from a USA focused organization to a North America focused organization. This will be an ongoing effort. One important step toward this goal is to construct a multi-national plenary session for the 2015 National Conference in Indianapolis, Indiana. This session will include a plenary address from a representative of the major regulatory organizations responsible for regulatory oversight of the food, drugs, medical devices and biologic products in Canada, the USA and Mexico. These organizations include;

- Canada = Canadian Food Inspection Agency (CFIA) and Health Canada (HC)
- Mexico = Federal Commission for the Protection Against Health Risks (COFEPRIS)
- USA = Food and Drug Administration (FDA) and US Department of Agriculture (USDA)

The Committee has identified potential speakers to fill these roles and will submit names to the Board upon request.

**Recommendations:** Charge complete – continue next year.

### **Executive Committee Action:**

Approval



Disapproval



Date

6/4/15

**Charge #2:** Lead/Partner/Create an alliance for 3<sup>rd</sup> party auditors for uniformity in training and certifications.

**Discussion:** The Committee has devoted much time to the exploration of this charge. The actual development of such a 3<sup>rd</sup> party alliance is well beyond the scope of this Committee. However, the Committee attempted to define methods to meet this charge. In doing so, the Committee chose to address this task by focusing on food and the international manufacturing and distribution of food in today's global environment. The Committee agreed that the ultimate goal of an internationally recognized and certified 3<sup>rd</sup> party program was the first step toward mutual reliance between regulatory bodies. The Committee agreed that certain criteria would have to be defined.

1. Regulatory bodies would have to approve of the work conducted by a 3<sup>rd</sup> party auditor.
2. 3<sup>rd</sup> party audits work would have to be consistent between auditors.
3. 3<sup>rd</sup> party auditors must receive the same or equivalent training and be certified to have the competencies required to conduct audits of certain food processes.
4. Regulatory bodies would be expected to approve of the training programs.
5. Metrics of achievement for certification programs would have to be agreed to by regulatory bodies.
6. 3<sup>rd</sup> party auditors must be certified by programs that meet the requirements of the regulatory bodies asked to accept the work of the 3<sup>rd</sup> party auditor.

*\*Responsible for submission of reports*

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For these criteria to be met, there must be a training and certification program that is recognized and accepted by regulatory bodies who might rely on the work of 3<sup>rd</sup> party auditors to reduce or avoid duplication of effort between regulatory bodies, internationally and within the boundaries of their own countries. Whereas all governmental regulatory bodies have their own training programs, they may not all be equivalent and regulatory bodies may not automatically accept the work of other regulatory bodies without first approving the training programs of those regulatory bodies. It therefore seems appropriate that for regulatory bodies to accept the work of other regulatory bodies, within their own countries, or internationally, they must agree on the training and certification program.

The Committee discussed the training programs currently in place for CFIA, HC, COFEPRIS and FDA. All had advantages and strong points, although none was without room for improvement. The discussion also revolved around the issue of one country approving the training program of another country over its own. This led to the discussion of finding and endorsing a 3<sup>rd</sup> party training program which would meet the criteria defined and be acceptable to multiple regulatory bodies in other countries so that they may adopt a mutual reliance program by accepting work conducted by 3<sup>rd</sup> party auditors certified thru a 3<sup>rd</sup> party training program which is accepted by multiple regulatory bodies. In this vein, the Committee is evaluating the Global Food Safety Initiative (GFSI) program and recommends that the Board allow the Committee to further explore this option. Additionally the Committee recommends that a workshop be conducted by GFSI at the 2015 Annual Conference to allow for evaluation and consideration of the GFSI program model for a global 3<sup>rd</sup> party audit alliance.

**Recommendations:** Continue the charge

**Executive Committee Action:**

Approval



Disapproval



Date

6/4/15



2014-2015 IGR Final  
Report-Attachment 1

*\*Responsible for submission of reports*

## IGRC Meeting Notes

January 30, 2015

1. Because the Committee has completed our charges given us by the AFDO Board, we agreed to meet monthly rather than bi-weekly. The next meeting will be Friday, February 27, 2015, 9:00am Pacific Standard Time. We will update the Outlook meeting invitation.
2. We agreed to request that AFDO invite the speakers shown below for our IGRC meeting from 2pm – 4pm, on Sunday, June 21, 2015 at AFDO's 2015 Annual Conference in Indianapolis, Indiana, June 20-23, 2015.
3. Bob Scales, Health Canada, will be transitioning out of the Co-Chair position this year after the June Conference. Ken Moore will transition into the Co-Chair position. Mark Roh, FDA, will be retiring April 3, 2015. Another FDA employee will transition onto the Committee. LaTonya Mitchell, will represent FDA as Acting Co-Chair starting in March 2015.

IGRC Meeting, Sunday, June 21, 2015

2:00pm – 4:00pm

- Update overview on the FSMA Import Rule – FDA speaker **Invite Todd Cato, Dallas District Director or Roberta Wagner, CFSAN Deputy Director for Compliance**
- Update overview on the Canadian Import Rule – CFIA speaker **Nicole Bouchard-Steeves identifying speaker from CFIA**
- Overview of Health Canada's Openness and Transparency Initiative of posting inspection results and ratings **Invite Ken Moore, Health Canada**
- Update overview on Mexico's enhanced import and export policies **Invite Ricardo Cevazos Cepeda, COFEPRIS**
- Feedback from Canadian and Mexican officials on the impact of FDA's new import rules and policies to the Mexican and Canadian regulatory efforts and their industries. **All speakers will participate on facilitated panel. Focus will be primarily on foods. However, drug and medical device issues will be discussed if requested by the audience.**