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Dr. Arpad Ambrus, Chair
Codex Committee on Methods of Analysis and Sampling (CCMAS)
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RE: DISCUSSION PAPER ON ELABORATION OF PROCEDURES FOR REGULAR UPDATING OF METHODS

AOAC International would like to congratulate the Delegation of Brazil for their efforts in preparing this document. We have had the opportunity to review the Discussion Paper and note that sections a) and b) of the "issues raised by the electronic working group" as well as "recommendations" 2. c) and e) pertain to information published by AOAC International. Some delegates may not be familiar with these publications. AOAC International feels that it is important to make these documents available to CCMAS Delegates in order to have an informed discussion. We are therefore providing copies of the following publications:

1) AOAC International Official Methods of Analysis, Appendix N: "ISPAM Guidelines for Validation of Qualitative Binary Chemistry Methods"
2) Methods of Analysis for Nutrition Labeling (1993), Chapter 7, pages 115 – 120, "Food Matrix Organizational System Applied to Collaborative Studies"

1) Guidelines for Validation of Qualitative Binary Chemistry Methods

Analysis of the performance of qualitative, binary methods, those that give one of two results: detected or not detected, require different statistical treatments than quantitative methods. The POD approach provides method performance information in terms of the Probability of Detection at a particular concentration near the lowest limit of application of a method rather than trying to establish a Limit of Detection. Method performance expressed as POD provides method users with a more complete description about the performance of a qualitative method, including how much this probability may vary.

As approved by the AOAC International Stakeholder Panel on Alternative Methods (ISPAM) in March 2013, the Guidelines for Validation of Qualitative Binary Chemistry Methods Annex A refer to three statistical analysis models, which are based on the POD approach. The Annex explains the utility of the models. Guideline users may choose the statistical model that best applies to their application.

2) Food Matrix Organizational System Applied to Collaborative Studies
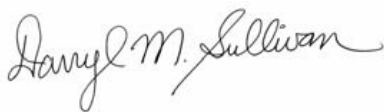
In 1990, under the Nutrition Labeling and Education Act (NLEA), food labels in the United States were required to display the nutritional content of nearly all packaged foods. AOAC International formed a Task Force to address the analytical demands of the NLEA. A major challenge identified by the Task Force was the need to be able to validate methods for all foods rather than a specific food or food group. Validation studies based on specific foods or food groups would require very large numbers of samples of different foods to be evaluated, thereby making such studies very complex and difficult to undertake. A systematic approach to classifying foods based on their chemical composition was developed in order to facilitate validation studies for all foods in a manageable way.

The key to the system is that the behaviour of a given food in an analytical method is generally related to the proportion of fat, protein and carbohydrate excluding moisture and ash. These components comprise the three points of the Food Triangle. The Food Triangle may be evenly divided into nine sectors into which any food may be placed according to its basic chemical composition. By carefully choosing an appropriate number of different foods from each sector, method validation studies can cover virtually the entire range of food compositions. The Food Matrix Organizational System Applied to Collaborative Studies as published by AOAC International in the Methods of Analysis for Nutrition Labeling (1993), Chapter 7, pages 115 – 120 describes the Food Triangle approach for validation studies for all foods and gives examples of its application.

AOAC International would like to emphasize that this approach was elaborated for nutrition labeling purposes but may be applied to other food analytes as an indicator of method performance in foods of varied composition. The publication notes that the approach may identify that methods as ineffective for certain food matrices in certain sectors and that the method limitations identified by the approach may be further investigated. As with all validated analytical methods, analysts must ensure that a method performs suitably for any new matrix tested.

AOAC International is pleased to provide these documents to the CCMAS Delegates attending the 35th Session and hopes that these will be useful in facilitating the review of the **DISCUSSION PAPER ON ELABORATION OF PROCEDURES FOR REGULAR UPDATING OF METHODS**.

Sincerely,

Darryl M. Sullivan
Secretary, AOAC International Board of Directors
AOAC Representative to the 35th Session of CCMAS