

Announcement of a Collaborative Study to Validate *in vitro* Methods to Determine Food Protein Digestibility for the Purposes of Nutrition Labeling for Consumer Foods in North America

The Protein Committee of the Institute for the Advancement of Food and Nutrition Sciences (IAFNS) (<https://iafns.org/>) is sponsoring a Collaborative Study to validate a well-established static *in vitro* method (pH stat and pH drop) for determining protein digestibility. The objective is to provide the science base that would support regulatory approval for this *in vitro* method to calculate the Protein Digestibility Corrected Amino Acid Score (PDCAAS), a measure of protein quality, which currently requires the use of animals for determining protein digestibility in order to make protein nutrient content claims. Dr. James House, Professor, University of Manitoba, has been contracted by IAFNS to lead the Central Laboratory for the Collaborative Study.

Background. The reliance the US Food & Drug Administration (FDA) and Health Canada on *in vivo* rodent bioassays to measure protein digestibility for PDCAAS or PER for quality represents a major barrier for innovation in the development of high quality protein foods at a time when there is strong public opposition to the use of animals for research on consumer products. Suppliers of protein ingredients are challenged to concurrently provide evidence of protein quality to support protein content claims AND evidence that products haven't been tested on animals, while suppliers to those seeking Vegan Certification cannot meet current requirements for protein quality assessment. As a result, suppliers of novel protein ingredients in North America often choose to not measure protein quality using the approved *in vivo* method. Although research to develop improved measures of protein quality (e.g. *in vitro* DIAAS) are ongoing, results are years away from implementation. In the meantime, the proposed *in vitro* protein digestibility method commonly used in research labs provides an immediate, scientifically, and ethically sound approach to encourage more food manufacturers to measure and maintain protein quality in foods being developed with plant and alternative protein sources in North American.

How will the Collaborative Project Goal be Achieved? A minimum of 8 participating laboratories, as required to be validated by AOCS for approval as an Official Method, will be provided a set of food protein samples whose digestibility has already been established in order to show equivalency with the *in vitro* method. Results will be evaluated by AOCS to determine whether the interlaboratory performance of the method meet the criteria for approval as an Official Method. Results will be published in an appropriate peer-reviewed journal. The final AOCS approved method and data will be shared with the FDA and Health Canada for consideration as methods that can be used for calculating PDCAAS for use in protein content claims.

Participating Laboratory's Eligibility and Commitment. Laboratories interested in participating in the Collaborative Study should provide evidence of a) experience with the pH stat or pH drop method and b) capacity to execute the required analyses. Participating laboratories will be selected and contracted by the Coordinating Laboratory. A virtual/in-person hybrid workshop will be held in October 2022 with all participating labs for input on method details, reagents, and test samples. Final versions of the method protocol as a result of the Workshop, will be reviewed by the Uniform Methods Committee of AOCS to ensure that the method descriptions meet the accrediting body requirements prior to conducting the Collaborative Study. The final protocol and 10-12 study samples will be provided to the participating labs. After completion of the Collaborative Study, statistical analyses will be conducted according to the recommendations of the accrediting organization.

Remuneration. All not-for-profit laboratories will receive \$10,000 to cover the costs of personnel and reagents (other than the test samples) needed to perform the required analyses. For-profit laboratories will not receive any financial compensation and their participation will be considered as a in kind contribution to the overall project and will be so acknowledged in the resulting publication.

To be considered as a testing lab, send the following information to MBprotein@umanitoba.ca by August 26, 2022

1. Lab PI responsible for the project if selected with email and phone contact information.
2. Evidence documenting experience using pH stat or pH drop method, preferably in peer reviewed scientific literature but exceptions will be considered.
3. Describe staffing and laboratory capabilities that will be utilized in performing determined tests within the next 8 months.
4. Any other key considerations relevant to the project (e.g., time limitations, etc).