

AGREEMENT OF COOPERATION

between

AOAC INTERNATIONAL and Nordic Committee on Food Analysis

This AGREEMENT is entered into as of the 9th day of September in the year 2019, between **AOAC INTERNATIONAL** located at 2275 Research Boulevard, Suite 300, Rockville, Maryland, USA, (hereafter referred to as AOAC), and **Nordic Committee on Food Analysis (NMKL)**, located at the National Food Institute, Technical University of Denmark, Kemitovet, Building 201, 2800 Kgs. Lyngby, Denmark (hereafter referred to as NMKL).

NMKL was established in 1947 and consists of chemists, microbiologists, sensory analysts and statisticians from the five Nordic countries: Denmark, Finland, Iceland, Norway and Sweden. NMKL elaborates validated chemical, microbiological and sensory analytical methods for food and feed analysis, issues guidelines (procedures) for laboratories and users of their services, and arranges courses and seminars. Organizationally, NMKL is linked to the Nordic Council of Ministers.

NordVal International (hereafter referred to as NordVal), a committee under NMKL, serves as an independent third-party, reviewing and certifying proprietary chemical and microbiological methods/test kits. NordVal certification assures an assessment of the methods performance characteristics and that performance is found to be in compliance with its claims. NordVal focuses on microbiological and chemical methods for the analysis of foods, water, feeds, contact surfaces and primary production samples.

AOAC is a globally recognized, independent third-party, not-for-profit standards development association founded in 1884. AOAC serves the analytical community by engaging stakeholders to develop voluntary consensus standards for methods and providing analytical methods that demonstrate fitness for purpose and confidence in analytical results.

The AOAC Research Institute (hereafter AOAC-RI) is a division of AOAC. The AOAC-RI serves as an independent, third-party, nongovernment administrator of the AOAC conformity assessment program known as the *Performance Tested MethodsSM* (PTM). The AOAC *Performance TestedSM* certification mark

is a registered service mark of AOAC INTERNATIONAL and use of the certification mark is governed through an executed AOAC Certification Mark License Agreement.

The AOAC *Official Methods of Analysis*SM (OMA) program is designed to provide validated methods that can be used with confidence by regulated industry, regulatory agencies, contract research organizations and testing laboratories, and academic institutions. Adopted methods are published in the *Official Methods of Analysis of AOAC INTERNATIONAL* compendium. Methods published in the compendium undergo rigorous scientific scrutiny to demonstrate the highest level of confidence in a method. Both the PTM and OMA are programs and registered service marks of AOAC INTERNATIONAL.

I. TERMS AND CONDITIONS

AOAC and NMKL enter into this Agreement of Cooperation to open a formal channel of communication to discuss topics and projects of mutual interest and to evaluate methods submitted to the NMKL, NordVal International, AOAC-RI, and/or AOAC method programs according to the following terms and conditions:

1. Execute this Agreement solely based upon submitted and processed applications of method developers which clearly indicate the intention of having a bilateral validation study that could result in a method approval and/or certification by NMKL, NordVal, AOAC-RI, and/or AOAC.
2. Establish communication to execute this Agreement when an application is received from a method developer that indicates the intent for one method evaluation study and subsequent review by more than one method evaluation organization.
3. Use of mutually accepted independent laboratory to draft protocols and manuscripts as well as oversee data collection using format(s) for each organization.
4. Develop a bilateral method validation testing protocol with clearly stated acceptance

criteria that is acceptable and approved by both method evaluation organizations, (e.g., within microbiology using ISO 16140-2/NordVal protocol and *Official Methods of Analysis of AOAC INTERNATIONAL* - Appendix J or most current AOAC guidance).

5. Conduct peer reviews of bilateral protocols, validation manuscripts, and other method information as needed according to each organization's policies, procedures, and rules.
6. Render decisions on approvals of methods and issue approval documentation (e.g., certification) according to each organization's policies, procedures, and rules.
7. Review and/or renew approval or certification according to each organization's policies, procedures, and rules.
8. Progress and rules of this cooperation must be transparent, and updates can be communicated through status updates during annual or periodic meetings and conferences of each organization.
9. For proprietary methods: All shared information pertaining to the evaluation of alternative methods in either the NordVal certification program or PTM program are confidential between AOAC-RI, NordVal, and the alternative method developer. The following items are confidential information:
 - a) The names of alternative methods and their manufacturers with alternative methods under review; or who are discussing the possibility of submitting an alternative method for review; or who have submitted alternative methods that the AOAC RI or NordVal has declined to certify.
 - b) The contents of data submissions; the results of independent testing; the comments of expert reviewers and/or independent testing laboratories; and the progress or status of alternative methods under evaluation.
 - c) The progress of negotiations on license, indemnification, or other agreements with specific alternative method manufacturers; including the fact of, and progress of an

appeal by an alternative method manufacturer.

10. For non-proprietary methods: When relevant the organizations can jointly adopt each other's methods. The method shall be named an AOAC-NMKL method and an NMKL-AOAC method, depending on which organization first elaborated the method. The organization adopting may make editorial changes, such that it complies with the practice of the organization. In the case of collaborative projects, the organization providing the "study director" (associated referee) shall be mentioned first.

II. ASSUMPTIONS

Both AOAC and NMKL enter into this Agreement according to the aforementioned terms and conditions with the following assumptions:

1. Both AOAC and NMKL will identify the administrative and technical personnel that will work together to provide each program's administrative support and will be working directly to facilitate the method validation protocol and validation manuscript development, as well as facilitate data collection and peer reviews.
2. Expert laboratory or mutually accepted independent laboratory will provide both AOAC and NMKL with copies of documentation in each organizational program's format for review and final copies after approval.
3. Method validation study protocols will include and the subsequent study(ies) will use the appropriate and mutually agreed upon reference method, if one exists.
4. Each organization shall notify the other of any additional information, process, or data required that is apart from the bilateral method validation approach.
5. This Agreement is **not** a reciprocity arrangement. This Agreement includes no financial support or financial reimbursement between AOAC and NMKL direct or in-kind. Each organization will work with the method developer, which will be responsible for remittance of program fees assessed by each organization.
6. This Agreement is a bilateral organizational approach to validating one method using one validation study data collection for two organizations. This bilateral program validation

approach is designed and will be administered to fulfil the requirements of both individual organizations' programs. Each participating organization will maintain and operate its own policies, procedures, rules, and fee structure.

III. ADVANTAGES AND BENEFITS

The benefit for the method developer is that there is one validation that meets both organizational programs' requirements. This approach ideally reduces the economic barrier of requiring separate studies. This approach also facilitates increased and improved cooperation and efficiency.

IV. EFFECTIVE DATE AND TERMINATION

This Agreement is in effect from the date of the last signature. Either party to this Agreement may submit a notice of intent to terminate this Agreement at any time.

In the event that issues arise, both parties shall make every attempt to amicably and mutually resolve the issue. If an issue is outstanding and cannot be mutually and satisfactorily resolved, both parties can agree to terminate this Agreement in writing, and the termination shall be effective on the date stated in the termination letter.

V. DELIVERABLES

Specific deliverables include the following:

1. Inter-organizational administrative and technical communication and cooperation is initiated for each method project upon each organization's receipt of an application requesting the evaluation of a method by AOAC, AOAC-RI, NMKL, and/or NordVal.

2. AOAC will provide necessary personnel and project management team contact information to work with an expert laboratory and to facilitate AOAC reviews and approvals.
3. NMKL will provide necessary personnel and project management contact information to work with AOAC personnel and project management team and to draft protocol, conduct study, and facilitate reviews.
4. Bilaterally approved method validation testing protocols.
5. Method validation manuscripts formatted to each organizational program's requirements.


VI. SIGNATURES

IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Agreement as of the date set forth above.

AOAC INTERNATIONAL

NAME: David B. Schmidt
TITLE: AOAC INTERNATIONAL Executive Director

SIGNATURE:



DATE:

9-9-19

Nordic Committee on Food Analysis

NAME: Nina Skall Nielsen
TITLE: NMKL Secretary General

SIGNATURE:



DATE:

9-9-2019
