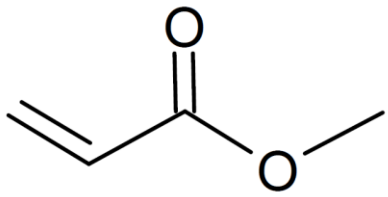
In Food & Agriculture, We Set the Standard

Voluntary Consensus Standard for the Determination of Acrylamide to Address Analytical Method Gaps for Food Matrices.



AOAC 2021 Initiative

Stricter regulatory approaches to addressing the formation and presence of acrylamide in high heat processed foods are on the horizon. Consensus method performance standards to support the development and adoption of official methods of analysis to determine acrylamide in foods to meet new regulatory requirements in a wide variety of matrices susceptible to acrylamide formation will be essential.

AOAC INTERNATIONAL is proposing the establishment of a working group to develop a voluntary consensus standard (or standards) for the determination of acrylamide to meet new regulatory requirements. The Working Group will develop one or more (as deemed necessary by WG experts) Standard Method Performance Requirements, SMPRs® for acrylamide in the high heat processed food products. Priorities will be set by an established Advisory Panel (see below).

Background

Acrylamide (CH_2=CHC(O)NH_2) is a low molecular weight organic compound widely used in many manufacturing processes and industrial products. In 2002, acrylamide was recognized as a contaminant in certain foods. Acrylamide is not a food additive, but forms naturally during high-temperature cooking processes such as frying, roasting, and baking. During these processes, acrylamide can be formed from the reaction of the free amino acid asparagine with reducing sugars, such as fructose and glucose. Processed foods most commonly susceptible to acrylamide formation are those made from plant-derived products involving potatoes (French fries, chips), grains (some cereals, breads, biscuits, cookies, crackers, crisps), nuts, cocoa, and coffee.

Since the discovery of acrylamide in foods due to high-heat processes, toxicology studies, analytical method development, and food surveys have been conducted to determine, in concert, exposure levels based on diet and its impact on public health. The potential toxic effects of acrylamide in food were recognized in a joint FAO/WHO report in 2002[1]. It has been classified as a probable human carcinogen (Group 2A) by the International Agency for Research on Cancer (IARC).

Studies on acrylamide and its major metabolite glycidamide, conducted by the U.S. Food and Drug Administration (FDA) under the auspices of the U.S. National Toxicology Program (NTP), found that each caused several (and similar) types of cancer in animals and were indicative of a strong carcinogenic response[2]. The result was identifying acrylamide as "reasonably anticipated to be a human carcinogen." Likewise, the US Environmental Protection Agency (EPA) labeled acrylamide as 'likely to be carcinogenic to humans'[3].

The effects of dietary exposure to acrylamide on human health remain inconclusive. In addition to consideration given to consumption patterns, many other factors have been identified. Acrylamide has been shown to accumulate when cooking is done for longer periods or at higher temperatures. The results of extensive regulatory surveys conducted through the FDA Total Diet Study, TDS (2002-2006 and 2011-2015)[4] show that the amount of acrylamide formed in foods is also highly variable due to such factors as crop variability, recipe design (the manufacturing process) and process controls.

Regulators had been reticent to imposed strict regulatory limits (maximum levels, MLs) on acrylamide content in foods. Instead, the focus centered on documenting exposure assessments; providing dietary survey results; providing mitigation strategies; and publishing guidance documents and codes of practices for business to reduce the presence of acrylamide in foods.

In a scientific opinion in 2015, the European Food Safety Authority (EFSA) reconfirmed their stance on the carcinogenic nature of acrylamide. In 2017, the Commission Regulation (EU) 2017/2158 established and adopted mitigation measures and benchmark levels for the reduction of the presence of acrylamide[5]. Though intended to be voluntarily implemented by food business operators, results were deemed too variable and discussions to establish maximum levels (MLs) in foods began. In 2020, a draft resolution was developed that called for the establishment of MLs for acrylamide in biscuits and rusks for infants and young children (150 µg/kg) and in baby foods and processed cereal-based foods for infants and young children (without biscuits and rusk (40 µg/kg). Furthermore, it called for a re-examination of benchmark levels in other food categories for adoption of additional MLs.

In the US, the FDA has remained consistent in their strategy by continuing to monitor levels of acrylamide in certain foods as part of the TDS; and, by providing regulatory guidance documents and fact sheets to both industry (growers, manufacturers, and food service operators) and consumers about how to reduce acrylamide formation.

Conversely, the State of California has listed acrylamide as a carcinogen on the Proposition 65 list of chemicals since 1990 and as a developmental and reproductive toxin since 2011[5]. These actions have led to many litigations. In 2020, Proposition 65 warnings are now being proposed for acrylamide only in those food susceptible to its formation and that do not meet mitigation practices to lower acrylamide levels to the lowest level currently feasible as set forth by the California Office of Environmental Health Hazard Assessment[6].

Current Analytical Methods and Recognized Challenges

Since 2002, there have been several methods developed and used for routine acrylamide analysis of various foods, including the European standard method EN 16618:2015[7] or the method developed by the U.S. Food and Drug Administration.[8,9]

The disparate regulatory landscape, the move towards establishing regulatory MLs and lower benchmark levels, the expansion of food matrices identified as susceptible to acrylamide formation and the challenges faced by testing laboratories and food producers reinforce the need for the development of consensus performance standards and the adoption of official methods of analysis. Such an effort would address the growing need for a more robust method that would provide broad applicability and ensure greater analyte recovery while minimizing noted matrix-derived interferences - all necessary elements for providing greater accuracy in acrylamide quantification.

Seeking Support

The Acrylamide Advisory Panel will be comprised of funding organizations to determine initial priorities and working group strategies. This panel will meet quarterly to review progress and consider additional objectives based on working group accomplishments. The projected funding level needed to complete this initiative as described is $80,000. We are asking organizations to join this important project for a contribution of $10,000. Other levels of contributions will be considered as well*. Services included in this fee are described in Appendix 1.

Benefits for You

Method developers

- Influence the development of consensus standards, which will be used by AOAC Expert Review Panels to evaluate your candidate methods for possible adoption as AOAC *Official Methods of Analysis*.
- AOAC *Official Methods of Analysis* will be the benchmark for trade resolutions, instill consumer confidence, and contribute to consumer safety.

Food manufacturers or food distributors:

- Ensure that the 2021 project priorities meet your needs through AOAC INTERNATIONAL's unique standard development process,
- Encourage the development of *Official Methods* which provide the highest level of analytical confidence for determination of acrylamide levels in a wide range of food types,

- Provide a validated analytical means needed to meet regional and internationally adopted regulatory requirements,
- Protect producers and consumers alike, maintain the reputation of products and ultimately improve the quality and safety of the food supply.

For all:

- Create much-needed reference methods for commodities that do not currently exist,
- Generate reliable data for effective compliance-driven quality control of food materials and products.

**AOAC INTERNATIONAL will continue to explore a multi-tiered funding schedule to avoid any unintended barrier to the ultimate success of this project and to encourage as many stakeholders to get involved as possible.*

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References

[1]Report of a Joint FAO/WHO consultation, "Health Implications of Acrylamide in Food, 25-27June 2002.

[2]Report on Carcinogens, Acrylamide, National Toxicology Program, Department of Health and Human Services, Fourteenth edition, 2016.

[3]Toxicology review of Acrylamide (CAS No. 79-06-1) Mrc 2010, U.S. Environmental Protection Agency, Washington, D.C.

[4]Survey Data on Acrylamide in Food, https://www.fda.gov/food/chemicals/surveys-data-acrylamide-food.

[5]https://oehha.ca.gov/proposition-65/chemicals/acrylamide.

[6]https://oehha.ca.gov/media/downloads/crnr/regtext080720.pdf.

[7]EN 16618:2015 Food analysis. Determination of acrylamide in food by liquid chromatography tandem mass spectrometry (LC-ESI-MS/MS)

[8]Roach, J.A.G.; Andrzejewski, D.; Gay, M.L.; Nortrup, D.; Musser, S.M. *J. Agric. Food Chem.* **2003**, *51*, 7547-7554.

[9]Andrzejewski, D.; Roach, J.A.; Gay, M.L.; Musser, S.M. *J. Agric. Food Chem.* **2004**, *52*, 1996-2002.

APPENDIX 1

The base fee per Working Group is $80,000 USD and includes:

- ***Advisory Panel Meetings****. AOAC will hold an Advisory Panel Meeting to identify renowned subject matter experts and to identify additional key authorities and experts to participate on AOAC working groups.*
- ***AOAC Stakeholder Meeting****. Working Group Chairs will present the Working Group launch presentation and the stakeholders will refine fitness for purpose.*
- ***AOAC Working Group Meetings****. The Working Groups will hold a series of teleconferences, as needed, to complete the draft SMPR(s).*
- ***AOAC Stakeholder Meeting****. Working Group Chairs will present draft SMPRs for approval by the stakeholders. Stakeholders will deliberate and reach consensus on and thereby approve a final version of the SMPR(s).*
- ***Publication Costs.*** *SMPR(s) approved by the stakeholder community will be published in A*OAC venues (i.e., *Official Methods of Analysis of AOAC INTERNATIONAL* and AOAC Website).
- ***Training and education materials/webinar(s) for method developers.***

Additional Fees (as applicable):

1. Application Fees for *Official Methods*^{SM} Review - $35,000 USD per method[1]:
   - Includes recruitment of Expert Review Panel (ERP) Members (Volunteer Experts),
   - Includes Preparation and Review of Methods for Review,
   - Includes ERP Orientation and Facilitating ERP Meetings,
     - Initial in-person meeting and, if methods are adopted, maintenance of ERP over the two (2) year method tracking period,
   - Includes ERP review of Method Modifications during the 2-year tracking period,
   - Includes Publications of methods and method manuscripts.

2. Application Fees for Modifying or Extending an Official Method of Analysis - $10,000 per method:
   - Includes Preparation and Review of Methods for Review,
   - Includes ERP Orientation and Facilitating ERP Meetings,
     - Initial in-person meeting and if methods are adopted, maintenance of ERP over the two (2) year method tracking period,
   - Includes ERP review of method during the 2-year tracking period, if required
   - Includes Publications of methods and method manuscripts.

Optional Enhancements (per method):

[1] Base application fee. AOAC Organizational Member discounts may apply.

- Consultation on validation test protocols: $3,000 USD
- Drafting Protocols & Review of Protocol: $3,000 USD
- Drafting of Method in AOAC Format: $2,000 USD
- Drafting of Method Manuscript in AOAC Format: $5,000 USD

NOTE: Travel costs of ERP members and coordination of laboratory work if needed are not covered. New application fees for resubmission will be required if an ERP does not approve the initial method submission.