

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 3

CX/MAS 19/40/3-Add.2

May 2019

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

40<sup>th</sup> Session

Budapest, Hungary, 27 -31 May 2019

### REVIEW OF CEREALS, PULSES AND LEGUMES METHODS (CEREALS, PULSES AND LEGUMES WORKABLE PACKAGE)

(Prepared by the AACCI)

#### INTRODUCTION

CCMAS38 (2017) agreed to continue efforts on the workable packages for the review and update of the *General Standards for Methods of Analysis and Sampling* (CXS 234-1999) as described in CX/MAS 17/38/6. CCMAS also agreed to pilot this effort through an update of all methods related to milk and milk products with the assistance of IDF, ISO and AOAC (REP 17/MAS, paras 58-59).

CCMAS39 (2018) agreed to proceed with the update on workable packages for (i) cereals, pulses and legumes; and (ii) fats and oils. The revision will be led by AACCI (cereals, pulses and legumes) and AOCS (fats and oils). All interested members and SDOs were invited to assist in this work as appropriate. The same protocol followed by IDF, ISO and AOAC in the revision of the dairy group workable package will be followed and enhanced.

AACCI reviewed the methods of cereals, pulses and legumes including methods for gluten-free foods in CXS 234-1999 as follows:

#### REVIEW OF THE METHODS FOR GLUTEN-FREE FOODS

##### History/Background

In 2005, CCMAS26 (CL 2005/21-MAS, ALINORM 05/28/23) discussed endorsement of the Mendez R5 method pending a collaborative study publication, that was in progress at the time. The method was temporally endorsed as Type I.

In 2006, CCMAS27 (CL2006/18, ALINORM 06/29/23) made the endorsement permanent as Type I, based on the original collaborative inter-laboratory study published, *European Journal of Gastroenterology & Hepatology* 2003; 15 (5): 465-474, which was organized and managed by the Working Group on Prolamin Analysis and Toxicity (WG PAT).

Recent work has updated the understanding of testing methods for gluten-free foods. We recommend and propose that CCMAS reconsider the methods endorsed in CXS 234 to reflect this understanding and information.

##### Current endorsement CXS 234:

Commodity	Provision	Method	Principle	Type
Gluten-free Foods	Gluten	Enzyme-linked Immunoassay R5 Mendez (ELISA) Method <i>Eur J Gastroenterol Hepatol</i> 2003; 15: 465-474	Immunoassay	I

In the past 13 years, both AACCI and AOAC Intl have supervised method validation studies using the same sandwich R5 ELISA for total gluten analysis, with sponsorship from R-Biopharm, the kit manufacturer.

Approvals for R5 method applications, reviews and status at AOAC and AACCI

In 2012, at AOAC the original Mendez collaborative study data was submitted and reviewed, and the method was granted OMA First Action status as AOAC method 2012.01, with the title “Gliadin as a measure of gluten in foods containing wheat, rye and barley” (R-Biopharm Catalogue R7001).

The matrices used in the original study were maize, rice, rice flour, maize flour, and wheat starch.

Also in 2012, AACCI performed a new multi-laboratory validation study using the same immunoassay kit, the R-Biopharm kit identical to the one approved by AOAC, but focused on corn samples.

The samples studied were corn bread, corn flour, and extruded corn snacks.

Subsequently, AACCI approved the method as AACCI Approved Method 38-50.01, with the title, “Gluten in Corn Flour and Corn-Based products by Sandwich ELISA.”

In 2016, the AOAC method was granted Final Action status, with a modification to the title. The title was changed to read: “Gliadin as a Measure of Gluten in Rice- and Corn- Based Foods.”

The AOAC Expert Review Panel that reviewed the method noted, that the original WGPAT collaborative study had only studied corn, rice and wheat starch. The AOAC panel granted Final Action status, with the condition that the title and scope of the official method be modified to reflect the matrices that were studied in the collaborative trial.

Testing for other cereal-based matrices - Oats

Oats are naturally gluten-free, but are usually grown in geographic regions where wheat and barley are grown. It is difficult to separate the crops in the open agriculture supply chain but it can be done using the rigorous means of Identity Preserved (IP) production and/or mechanical/optical grain sorting.

Both Canada and the USA provide a marketing option for labeling products including IP oats as Gluten Free, at the limit of 20 parts per million (ppm).

(<https://bit.ly/2lme3ia> and <https://bit.ly/2Za278l> )

In 2018, a new AOAC method for use in oat products was validated using R-Biopharm Sandwich ELISA Catalogue R7041 for Total Gluten. This method is OMA 2018.15, and is titled, “Gluten from wheat, rye, and barley in oats and oat products by quantitative sandwich ELISA.” The method was validated in 2018 by a multi-laboratory study (19 laboratories) on oat products including; oat groats, flaked oats, oat flour and extruded oat breakfast cereals. The validation showed balanced recovery for gluten from wheat, rye and barley sources in the oat products at 108, 137 and 110 % recovery respectively. (In press, Journal of AOAC International )

Current Status and Recommendation for CCMAS

AACCI and AOAC Intl recommend that the method endorsement for the R5 gliadin method should be updated to include:

1. Information from the subsequent review of the original method validation study by AOAC, that was subsequently revalidated by AACCI. In this case, AOAC method 2012.01 and AACC Method 38-50.01 should be considered as equivalent.
2. The method for gluten in oats AOAC 2018.15 as validated for the measurement of gluten in oat-based gluten free foods.

Proposed Modification

CCMAS is invited to consider

Commodity	Provision	Method	Principle	Type
Corn- and rice-Based Gluten-Free Foods (unfermented)	Gluten	AOAC 2012.01/AACC 38-50.01 (R5 sandwich ELISA method for gliadin)	Immunoassay	I
Oat-Based Gluten Free Foods (unfermented)	Gluten	AOAC 2018.15 (Total Gluten sandwich ELISA)	Immunoassay	I

## REVIEW OF METHODS FOR CEREALS, PULSES AND LEGUMES

AACCI appreciates the opportunity to update the members of CCMAS on the plan and progress to review the methods in Standard 234 for Cereals, Pulses and Legumes (CPL methods).

### The challenge for AACCI following CCMAS 39

In the past few years, different approaches suggested by first the countries who initiated the project (the workable packages), and then the standards organisations who responded to those packages were presented.

To help guide this work, AACCI visited with the CCMAS electronic working group (EWG) chaired by the United States of America (USA) and co-chaired by New Zealand to review the Dairy methods. We noted the questions presented in the EWG relating to the dairy group workable package, and also the concern with some commodity methods not included. We anticipated similar questions arising in the CPL discussions and decided to pre-empt the issue and start with all methods in CXS 234 that are applicable to these matrices.

AACCI noted also the development by the Dairy EWG chairs of questions to be answered by the reviewers. We examined the Method Review sheets developed by New Zealand: that included the review questions, information from the commodity standards, and additional information as relevant. This approach kept the need of the commodity standards in focus and also streamlined the review of certain methods across multiple analytes and matrices. We believe this approach would also benefit the work in CPL methods. And would provide a basic framework for CPL method reviews, although we will be interested to hear if the EWG would suggest any changes to those review sheets for future work?

### Conclusion

In view of the changing landscape and the many questions raised for CCMAS by the Dairy EWG, AACCI has decided to delay the completion of the CPL package until after the resolution of these issues. In the interim, AACCI has completed the task of identifying all CPL methods in CXS 234, and have this list available during CCMAS40 as a conference room document (CRD). AACCI welcomes any feedback from Codex members and observers on this list. AACCI is hopeful that after CCMAS40, AACCI will have clear direction and confidence to proceed with the preparation work for the review of the CPL methods.