CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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**Agenda Item 6** **MAS45/CRD10**

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**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING**

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# COMMENTS OF THE EUROPEAN FEDERATION OF ALLERGY AND AIRWAYS DISEASES PATIENTS' ASSOCIATIONS (EFA)

## Agenda item 6: Methods of analysis for precautionary allergen labelling

The "Electronic Working Group Discussion Paper on Recommended Methods of Analysis in Support of Precautionary Allergen Labelling" carried out a comprehensive review, gathering and assessing over 100 validation datasets for analytical methods. This review was based on the major international guidelines on development, validation, and performance, including:

- AOAC Appendix M (as specified in Guidance on Food Allergen Immunoassay Validation Methods of Analysis of AOAC INTERNATIONAL, 22nd Edition (New York, 2023; online edn, AOAC Publications, 4 January 2023), https://doi.org/10.1093/9780197610145.005.013)
- EN standards such as EN 17855 (ELISA), EN 17644 (LC-MS), EN 17254 (ELISA Gluten), and EN 15634 (PCR).

A review of interlaboratory validation studies and proven methods indicates that the primary focus is on enzyme-linked immunosorbent assays (ELISAs).

The primary critical issues identified in this evaluation are as follows:

### 1. Methodological Limitations and Harmonisation

- Method Suitability: Qualitative methods were also employed in the study, but they were deemed insufficient for accurately measuring the concentration of an allergen compared to a reference dose.
- Uniformity of Results: A harmonised and shared method for expressing analytical results is still lacking.

### 2. Critical Issues in the Use of Proprietary ELISA Kits

- Transparency and Reagent Substitution: The use of proprietary ELISA kits faces notable limitations. Manufacturers often do not provide clear and comprehensive details on reagent composition. Additionally, substituting components (for operator safety reasons) can impact kit performance.
- Incomplete Information: Specifications on calibrants (concentration and purity) and selected antibodies (monoclonal/polyclonal) are often incomplete;
- Validation and Food Matrix: Manufacturer-provided validations are often specific to certain matrices. The laboratory, therefore, remains responsible for verifying, on a case-by-case basis, their applicability to different samples and, in particular, for identifying any cross-reactivity with other molecules.
- Matrix Dependence: Analytical performance is strongly influenced by matrix characteristics (for example, the denaturation of egg white proteins due to high temperatures reduces their recognition by antibodies, leading to an underestimation of the allergen in heat-treated foods).
- Commercial Availability: The availability of commercial kits is often limited locally, preventing uniformity of use globally.

### 3. Standardization Needs

While awaiting the establishment of reference values for individual allergens, it is noted that:

- Harmonisation and Controls: The availability of harmonised and recognised official methodologies, along with control materials with suitable characteristics, is currently limited.
- Guidance Structures: National and EU bodies committed to offering guidance for methodological harmonisation have yet to be established.
- Laboratory Verification: Currently, each laboratory independently verifies or enhances the validation of the selected kit, defining specific analytical parameters, including uncertainty, on a case-by-case basis.

Finally, it is emphasised that the analytical methodologies discussed in the document and presented by EWG members are not exhaustive. It is hoped that additional methods capable of meeting CEN performance requirements and/or AOAC validation guidelines will be developed and employed commercially in the future, and that the methods included in the CCMAS response to the CCFL do not prevent their development.