

## **GUIDELINES FOR SETTLING DISPUTES OVER ANALYTICAL (TEST) RESULTS (CAC/GL 70-2009)**

### **1. SCOPE**

These guidelines provide guidance to governments on the procedures to resolve disputes which arise between food control authorities about the status of a food consignment<sup>1</sup>, when the assessment based on test results made in the importing country disagrees with the assessment made by the exporting country on the same lot<sup>2</sup>.

These guidelines only address disputes related to methods of analysis or laboratory performance and do not address questions of sampling. The procedure examines only the validity of the importing country's results on which non-compliance is alleged. It is recognised that disputes may arise from other cause(s), which should also be investigated<sup>3</sup>.

These guidelines do not cover microbiological test results.

### **2. PREREQUISITES/ASSUMPTIONS**

The procedure described in these guidelines is operable and effective only when the conditions listed below are met. Competent authorities should therefore ensure that these are satisfied wherever possible. These conditions are:

- both countries agree on using this guideline;
- laboratories<sup>4</sup> comply with quality assurance provisions and with the *Codex Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and the Export of Food (CAC-GL 27)*, and the laboratories have been designated by their respective Competent Authorities in both the importing and exporting countries;
- at least one representative sample<sup>5</sup> from the same food lot has been taken by the Competent Authority at import in accordance with established sampling plans and/or good sampling practices, where applicable; this sample has been split into three essentially identical parts for the purposes of primary analysis and for confirmatory analysis (reserve samples)<sup>6</sup>; the split reserve samples should be kept in a satisfactory condition for the appropriate length of time;

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<sup>1</sup> Status of the food consignment depends on the "interpretation" of the test result(s), in the light of measurement uncertainty, sampling error and the closeness of those test results to the limit. It could still be that the results do not differ by an amount which is significant, but nevertheless one result indicates conformity, but the other result does not.

<sup>2</sup> As defined in the General Guidelines for Sampling (CAC/GL 50 -2004).

<sup>3</sup> Possible reasons for disagreement may include one or several causes such as: the existence, appropriateness and statistical validity of the sampling plan used to assess the product; the allowances made for normal measurement error and within-lot product variation; differences in physical sampling procedures; differences in composition of the samples tested due to product inhomogeneity or changes occurring during storage and/or transport of the product.

<sup>4</sup> For the purpose of these guidelines, the word "laboratory" applies to both official and officially recognised laboratories. An official laboratory would be a laboratory administered by a government agency having jurisdiction empowered to perform a regulatory or enforcement function or both. An officially recognised laboratory would be a laboratory that has been formally approved, designated or recognised by a government agency having jurisdiction.

<sup>5</sup> This may be a set of samples. When the wording "sample" is used it might refer to a set of samples

<sup>6</sup> However, if the applicable sample has been split into two essentially identical parts, then the procedure as outlined might be followed, with the omission of the step described in section 4.

- laboratories report quantitative analytical results in the form of “ $a \pm 2u$ ” or “ $a \pm U$ ” where “ $a$ ” is the best estimate of the true value of the concentration of the measurand (the analytical result) and “ $u$ ” is the standard uncertainty and “ $U$ ” (equal to  $2u$ ) is the expanded uncertainty. The range “ $a \pm 2u$ ” represents a 95% level of confidence where the true value would be found. The value of “ $U$ ” or “ $2u$ ” is the value which is normally used and reported by analysts and is referred to as the “measurement uncertainty”; it may be estimated in a number of different ways (*see Codex Guidelines on Measurement Uncertainty, CAC/GL 54-2004*);
- laboratories/competent authorities report the sampling plan (including acceptance criteria) that was used and the analytical results that were used to determine the acceptance status, including any information necessary to interpret the results such as:
  - a) whether analytical results are expressed on a recovery-corrected basis (and if so the method by which recovery was taken into account and the recovery rate),
  - b) the units in which results are expressed, and
  - c) the number of significant figures.
- laboratories use specific methods of analysis, which have been endorsed by the Codex Alimentarius Commission (CAC) or use methods of analysis which comply with performance parameters which have been endorsed by the CAC when they are available. Otherwise, methods must have been validated according to the requirements of the CAC.

### **3. THE RESULTS AND PROCEDURES OF THE LABORATORY OF THE EXPORTING COUNTRY AND ITS COUNTERPART IN THE IMPORTING COUNTRY ARE COMPARED<sup>7</sup>**

The competent authorities have the option to agree on comparison of the background information of the analysis of the sample. In accordance with relevant Codex Guidelines<sup>8</sup>, the following information should be shared between competent authorities of the importing and exporting country to allow comparison of the results and procedures of the laboratory of the exporting country and its counterpart in the importing country. The relevant information covers:

- validation status of the methods of analysis used (including method-specific sample handling and preparation procedures within the laboratory);
- raw data (including spectral data, calculations, chemical standards used);
- results of repeat analysis;
- internal quality assurance/control (control charts, sequence of analysis, blank data, recovery data, uncertainty data, use of appropriate reference standards and materials);
- performance in relevant proficiency testing or collaborative studies;
- official accreditation status of the laboratories.

Each competent authority reviews its initial assessment on the basis of the additional information received from the other. This may lead to agreement on conformity or agreement on non-conformity, e.g. by recognising the validity of the results of only one of the two laboratories. In this way, the dispute is resolved without further analysis.

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<sup>7</sup> In cases where a dispute needs to be resolved quickly, for instance where perishable food is in question or where demurrage costs are high, it is recommended that the competent authorities should consider performing the steps outlined in sections 3 and 4 in parallel.

<sup>8</sup> See ANNEX to GUIDELINES FOR THE EXCHANGE OF INFORMATION BETWEEN COUNTRIES ON REJECTIONS OF IMPORTED FOOD (CAC/GL 25-1997): "Where imported food has been rejected on the basis of sampling and/or analysis in the importing country, details should be made available on request as to sampling and analytical methods and test results and the identity of the testing laboratory."

If the dispute still exists the competent authorities continue with the step in section 4.

#### **4. ANALYSING RESERVE SAMPLE**

A reserve sample is analysed, subject to it being established that sample integrity and the chain of custody have not been compromised and subject to agreement between the respective competent authorities on the following procedures for analysis of the sample(s):

1. the timeline, and the time of availability of the sample<sup>9</sup>;
2. the analysis of the reserve sample by either
  - the importing country's laboratory in the presence of an expert from the exporting country
  - or
  - a laboratory chosen by the exporting country;
3. the methods of analysis to be used by the laboratory.

If the original test result of the importing country and the result of the reserve sample differ by less than the critical difference  $\Delta$  that would be expected from measurement uncertainty of the results (see Annex), the importing country's original assessment of the lot shall stand, and the dispute is thus resolved.

If the dispute still exists, the measures outlined in section 5 of this procedure, using arbitration by a third laboratory, should be applied.

#### **5. ANALYSIS OF REMAINING RESERVE SAMPLE**

The remaining reserve sample should be analysed by a suitably qualified laboratory agreed on by the two countries, and a final assessment of conformity is based on the results from this laboratory. Failing agreement on the choice of laboratory the competent authority of the importing country can select a laboratory. The original result and the result from the reserve sample tested in the step outlined in section 4 are discarded. If possible this laboratory should be independent of the laboratory or laboratories whose results were compared in the step in section 4.

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<sup>9</sup> The dispute shall be resolved within the shortest possible time, which should not adversely affect the quality of the commodity during storage, where appropriate.

**ANNEX**

The critical difference  $\Delta$  between the two results to be compared is

$$\Delta = \sqrt{U_1^2 + U_2^2}$$

Where  $U_1$  and  $U_2$  are the expanded measurement uncertainties of the two results.

In case a set of samples is involved, a different formulation for the critical difference should be used.