

# VELTIA SA

## *Decision Rule for the Compliance of Samples Tested at Veltia Labs for Life*

### 1. Introduction

This procedure describes the Decision Rule used by the laboratory in cases where a Statement of Conformity is required. When a Statement of Conformity is provided, the following shall be clearly identified:

- The specific results to which the Statement of Conformity applies.
- Which specifications or parts thereof are met or not met
- The decision rule applied

The decision rule may:

- Be defined in legislative or other regulatory documents.
- Be predefined by the customer and accepted by the laboratory.
- Be decided by the laboratory, taking into account the level of risk, and communicated to the customer.

### 2. Prescribed Decision Rules

#### 2.1 Plant Protection Product (PPP) Residues in Food and Feed

Maximum Residue Levels (MRLs) are determined by Regulation (EC) 396/2005 and its amendments. According to the SANTE document, the acceptable expanded uncertainty  $U$  (95% confidence level,  $k=2$ ) for residue determination is 50%. The concentration of an active substance  $x$  is considered to exceed the MRL if  $x-U > \text{MRL}$ , in which case the sample is characterized as non-compliant.

#### 2.2 Water Intended for Human Consumption

Parametric values are determined in the Joint Ministerial Decision (JMD) Δ1(δ)/ΓΠ οικ. 27829/2023 (Government Gazette 3525/B/25-5-2023). The Decision Rule applies to the parameters included in Annex I of the aforementioned JMD.

In cases where the water originates from and/or will be consumed in another EU member state, it must be investigated whether that country's legislation has been harmonized with Directive 98/83/EC (as amended by Directive (EU) 2015/1787 and as currently in force in Greece) or with the more recent Directive (EU) 2020/2184.

According to the aforementioned Directives and the JMD, for the parameters included in Annex I, uncertainty is not taken into account as an additional tolerance. Consequently, the sample is considered compliant if  $x \leq L$ , where  $x$  is the measured value and  $L$  is the maximum acceptable value (parametric value) for the corresponding parameter. For borderline values (where the result and the uncertainty encompass the limit), the uncertainty must be stated in the Test Report.

# VELTIA SA

**Exception:** The compliance or non-compliance of a sample with the legislative limits for gross-alpha and gross-beta activity is evaluated and decided upon by the Greek Atomic Energy Commission (EEAE).

For all other cases of water, food, and feed analysis, the laboratory does not provide a Statement of Conformity unless requested by the customer.

## 2.3 Customer Specifications and/or Decision Rule

Specifications provided by the customer may be accepted if:

- They are stricter than the current national or European Legislation
- They are based on the Legislation of a Third Country.
- There is no relevant Legislation in place.

In such cases:

- The customer must submit the relevant specifications in writing.
- A relevant reference is made in the Test Report.

A decision rule specified by the customer may be accepted if it does not conflict with a Legislative or Regulatory Document. In this case, the Rule must be documented, and a relevant reference must be made in the Test Report.

In the event that no other Decision Rule is defined and the measured result  $x$  is compared with a single stated value  $L$ , the result is considered compliant at a 95% confidence level when  $x-2u < L < x+2u$ , where  $u$  is the standard uncertainty.

For the Veltia SA

The Quality Manager