



Certificates of Analysis and Wine Safety

1. Introduction

From a food safety standpoint wine is an inherently safe product¹. Despite this demonstrable fact, in nearly every economy certificates of analysis are demanded at some point in the trade process. Reasons given for these demands include providing assurance that the products pose no risk to health and safety, and to demonstrate that they meet local regulatory or commercial requirements. As this paper demonstrates, certificates of analysis are often not necessary at all, and certainly not to show that the products pose no risk to the health and safety.

In those exceptional cases where certificates are justified, the importing economy must have confidence in the analytical data contained in such certificates. Consequently, qualifications of the laboratory that produced the certificates must be recognized by economies involved to eliminate trade barriers and allow commerce to proceed smoothly and in a timely fashion.

Also, in those exceptional cases where certificates are justified, required data must be clearly defined in a manner that makes the requirements clear to producers and practical to measure and report without ambiguity.

Issues have arisen in international trade due to a lack of understanding that laboratory data has inherent analytical variability. Data contained in certificates of analysis should be evaluated by taking this into account.

2. Analysis Requirement

A typical justification for certificates of analysis is to ensure safety of the product for the consumer. Most analytical requirements related to certificates of analysis for wine are unsuited for this purpose since they are not related to health concerns, or require analysis to be performed where wine by its very nature will always be compliant (e.g., in the case of specifications for pathogenic micro-organisms in wine).

¹ FIVS (2016), *Microbiologically Wine is a Low Food Safety Risk Consumer Product*. Paris, France .

Requirements for certificates of analysis for various wine-importing economies have included over fifty different analytes. Some examples of these include²:

Appearance	Hybrids	Stability at -5°C
Bacteria, cultured	Iron	Sucrose
Calories	Lead	Sugar Free Extract
Citric Acid	Limpidity	Titrateable Acidity (TA)
Colour (sensory evaluation)	Methanol	Total Alcoholic Strength
Copper	Molecular Sulphur Dioxide (SO ₂)	Total Dry Extract
Density	pH	Total Sugar (Reducing Sugar - Inverted)
Ethanol	Reducing Sugar	Total Sugar
Free Sulphur Dioxide (SO ₂)	Remaining Extract	Total Sulphur Dioxide (SO ₂)
Fungus, cultured	Sorbic Acid	Volatile Acidity (VA)
Gas Pressure at 20°C	Specific Gravity	Volume per Bottle
Glucose + Fructose (sugars)	Stability at 55°C	Yeast, cultured

These example analytes can be grouped as follows: health and safety, wine quality and legality, additive levels, typical wine parameters, microbiological, and physical characteristics.

2.1 Health and Safety

Of this exhaustive list of tests, only total sulfur dioxide might arguably represent a true health and safety concern (and then only for certain susceptible individuals). However, the levels generally considered of concern in relation to possible health risks are very unlikely to be found in wine as they would result in an otherwise unpalatable (and consequently unmarketable) product. In addition, most markets for wine require that the presence of sulfites in the product be indicated on the label. Though methanol is considered a substance of concern for some beverages, the levels found in wine are well below those presenting issues related to health³.

It has been argued that analysis for the presence of heavy metals relates to health and safety concerns. In reality, typical levels found in wines produced according to common oenological practices, and consumed at typical levels, would not result in an ingestion of heavy metals that exceeds maximum intake levels specified by the Codex Joint Expert Committee on Food Additives (JECFA)⁴.

2.2 Wine Quality and Legality

Wine quality and legality might include the parameters ethanol, methanol, volatile acidity, and gas pressure. These classify wines with regard to their legal status (i.e., tax class) or are an indication of the care taken during winemaking, storage, and bottling. None of these substances pose health concerns at levels typically found in wine produced using good oenological practices.

² ETS Labs (2017), Analysis for Exports. St. Helena, California, USA.

³ FIVS (2016), *Methanol in Wine*. Paris, France .

⁴ World Health Organization (2013), Evaluations of the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

2.3 Additive Levels

Most additions made to wine in the course of its production involve the use of natural grape-derived substances to adjust the levels of the same components already present. The amount of such additions is consequently difficult to quantify by analysis. Analyses for other substances merely indicate how much of a given permissible additive was used during production, or was present in the original grapes. When used according to Good Manufacturing Practices (defined as using the minimum possible amount of a substance to achieve the desired technological result), these would not be present in wine at any levels which would be considered to pose a health risk according to JECFA, given typical consumption levels.

2.4 Microbiological

The microbiological category, which includes bacteria, yeast, and fungus, is in no way a health and safety concern for wine. Due to the low pH, alcohol, polyphenol and sulphite content of wine, no pathogenic microorganisms are able to survive in it⁵.

2.5 Physical Characteristics

Physical characteristics include appearance, color, limpidity (clarity), and stability and are not related to health and safety impacts but rather are subjective descriptors of wine characteristics. Such descriptors are subject to the changing fashion and style of products, so their use in a regulatory capacity is highly questionable, and could be considered barriers to trade as they have the potential to unjustly impact traditional styles from some regions.

2.6 Typical Wine Parameters

The remaining analyses can be considered typical wine parameters. These include pH, sugars, density, acidity, and the like. Since wine is made from natural grapes, these parameters typically fall within a narrow range of values, none of which is related to health and safety. Furthermore, any addition or supplementation of compounds which would affect these parameters would not make the wine of any public health concern. For this reason, these parameters should be excluded from any testing related to health and safety.

3. Overall Rationale for Analytical Certificates

In summary, the components of the exhaustive list of test parameters sourced from economies throughout the world are by their very nature either (1) not related to public health and safety, or (2) are very unlikely to reach harmful levels in wines produced according to good oenological practice.

Therefore, any analysis that an economy requires for a certificate of analysis would simply be regulatory in nature, rather than to promote the health and safety of wine consumers. Even alcohol, which is the sole analytical requirement specified by some international trade destinations, is usually required to be declared on the label of the bottle, as well as in the accompanying documentation. The rational conclusion to this study of wine analytes would

⁵ FIVS (2016), *Microbiologically, Wine is a Low Food Safety Risk Consumer Product*. Paris, France.

be that, from the perspective of product safety, there is not a need for certificates of analysis for international wine trade.

4. Laboratory Data for Analytical Certificates

If economies insist on the continued need for certificates of analysis, it is clear that data provided must be unambiguous and trustworthy to ensure smooth and unhindered commerce.

Required data should be clearly defined in a manner that makes the requirements clear to producers and practical to measure and report without ambiguity. Poorly defined requirements which are based on methodologies rather than actual analytical content of certain components in wine can make this impossible. An example is analysis of sugar which is variously defined as:

- the quantity of compounds capable of reducing an alkaline cupric solution,
- the combined quantities of saccharides and disaccharides,
- the amount of fermentable sugars present, or most simply as
- the amount of glucose, fructose and sucrose present.

These different definitions, as well as small variations in individual methods, can see the measured quantity of sugar in wine vary by more than 3 g/L between definitions, making any regulatory comparison meaningless. Any analytical testing requirement for a certificate of analysis should define the requirement in terms of a discrete chemical entity rather than the outcome of a specific methodology. The value can then be used with quoted measures of uncertainty, which should be supplied by the laboratory, to ascertain if the value conforms to a regulatory limit.

Required analysis should be defined in terms of discrete chemical entities and required uncertainty of measurement.

The majority of wine producers have analytical data available from their own laboratories generated during the production process. Due to its importance in production, it is in the producers own best interest that their laboratories provide accurate and precise results. In many cases, as is certainly appropriate, economies are willing to accept certificates of analysis produced with data from such production based laboratories. This acknowledges the nature of the requirements and that the data produced is fit for purpose.

It is important that such certificates can be produced in the country of origin. This allows producers to ensure that the product complies with relevant regulatory requirements before it is dispatched. Also reduced significantly are risks of dispute and the added costs for return or destruction of product. For place of origin testing to be accepted it is essential that the importing economy has high confidence in the data and the laboratory used to produce the certificate. The mechanism to achieve this is accreditation of the analytical laboratory to an internationally recognized standard which is accepted by the importing economy. In the area of laboratory analysis, the relevant international standard is ISO 17025.

The use of such ISO 17025 accredited laboratories, whether they are associated with producers, governments, or are third party commercial laboratories, to produce certificates of analysis should negate the need for repeat testing in market because the data already meets agreed upon standards.

Data produced by ISO 17025 accredited laboratories should be widely accepted throughout the world for use on certificates of analysis.

5. When Laboratory Results Do Not Agree

Laboratory results are subject to uncertainty by their very nature. In every laboratory (however proficient) small variations in temperature, analyst technique, analyte stability, and a great number of other factors cause variations in the final result. It should be noted that ISO 17025 takes this known variation into account, and each laboratory will have a known uncertainty for a given method that should be available with the result (e.g., 7.1 +/- 0.2 g/L).

Codex Alimentarius has also acknowledged that laboratory results are subject to variation, which increases as a percent of the reported value as the concentration decreases. They have stated that “it would be reasonable to anticipate that the (expanded) uncertainties reported by laboratories would be approximately the following”.⁶

Nominal Concentration	Typical Expanded Uncertainty	Expected Range of Results*
100 g/100g	4%	96 to 104 g/100g
10 g/100g	5%	9.5 to 10.5 g/100g
1 g/100g	8%	0.92 to 1.08 g/100g
1 g/kg	11%	0.89 to 1.11 g/kg
100 mg/kg	16%	84 to 116 mg/kg
10 mg/kg	22%	7.8 to 12.2 mg/kg
1 mg/kg	32%	0.68 to 1.32 mg/kg
< 100 µg/kg	44%	0.56 x concentration to 1.44 x concentration in ug/kg

* this effectively means that values falling within these ranges may be regarded as being of the same analytical population.

Taking the Codex guidelines into account, a result of 100 mg/kg for Total Sulfur Dioxide (SO₂), would include results between 84 mg/kg and 116 mg/kg, and would be regarded by Codex as “being in the same analytical population”. Put simply, they are both “correct”.

If this same principle is applied to enforcement, no action would be taken if the resulting

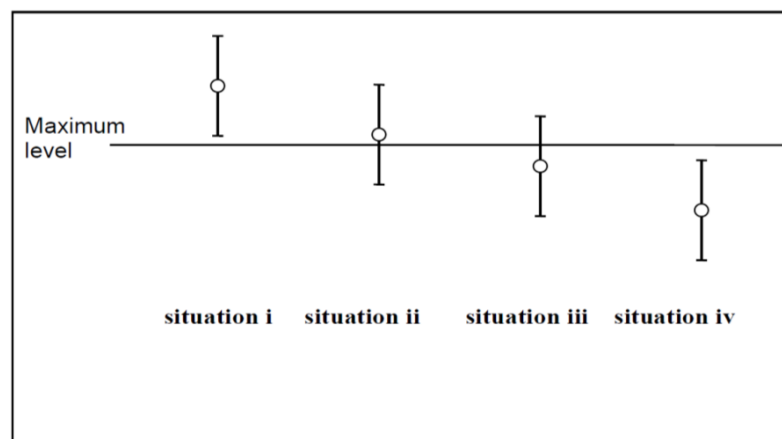
⁶ Codex Alimentarius Commission (2011). Report of the Thirty Second Session of the Codex Committee On Methods Of Analysis And Sampling, Budapest.

analysis showed that the analyte in question was within the uncertainty range. For example, if a regulated compound was found to be present at 110 mg/kg, and the legal limit is 100 mg/kg, no enforcement action should be taken; the concentration of this analyte is within the typical uncertainty range for the test.

Please note that this table contains the *typical* uncertainty. In reality, each analytical method as implemented has its own unique variation, and it is the responsibility of every laboratory, including and especially enforcement laboratories, to make available these uncertainty values in relation to their analyses.

To further illustrate this concept, Codex⁶ has prepared the following example:

...where the test result is compared against the specification consisting of a maximum level. It illustrates how the concept of measurement uncertainty could be taken into account when interpreting analytical results on a tested sample. This diagram demonstrates the importance of defining clear guidelines to allow unambiguous and objective interpretation of analytical results with respect to their measurement uncertainties.



Situation i

- The analytical result minus the expanded measurement uncertainty exceeds the maximum level. The result indicates that the measured analyte in the test sample is above the specification.

Situation ii

- The analytical result exceeds the maximum level by less than the expanded measurement uncertainty.

Situation iii

- The analytical result is less than the maximum level by less than the expanded measurement uncertainty.

Situation iv

- The analytical result is less than the maximum level by more than the expanded measurement uncertainty.

Based on this explanation, only the result in ***Situation i*** would result in enforcement action. The others would not. It is the practice of many authorities to take uncertainty into account before considering enforcement action.

Some authorities take into account the calculated measurement uncertainty of their methods. Others, when considering trace-level analysis for compounds like pesticides, do not take enforcement action unless the result is (1) greater than 150% of the tolerance level, and (2) has been confirmed by re-analysis, with the two results being no more than 30% apart from each other⁸.

On a final note, if enforcement action is considered, it is suggested that the importing economy provide a full set of supporting data to the exporting economy in advance. Contents of such a data package might typically include method validation data, calibration verification, and quality assurance data supporting the result in question.

Laboratory data has inherent analytical uncertainty and any results should be evaluated by taking this into account when considering enforcement action. When enforcement action is being considered, it is suggested that the importing economy contact the appropriate government authority of the exporting economy in an attempt to discern the source of any discrepancy.

6. Conclusions

Certificates of analysis are often demanded to allow products to enter an economy. Reasons given for these demands include providing assurance that the products pose no risk to the health and safety and to demonstrate that they meet local regulatory and commercial requirements. It has been demonstrated in this paper that since wine is an inherently safe product, and demanded analyses are often not related to health and safety, certificates of analysis for this purpose may not be necessary.

If a certificate of analysis is required, it is important that the definition of analytes provided refer to specific chemical entities and the uncertainty of measurement required of the analysis, and not be defined in term of arbitrary analytical methods. This will provide clarity to ensure that the wine meets regulatory requirements.

When certificates of analysis from accredited laboratories are required for compliance with regulatory requirements, the laboratories which perform this testing should comply with internationally recognized standards such as ISO 17025. Certificates of analysis from accredited facilities should be accepted in all markets without any requirements for in-market testing.

If discrepancies occur in the course of trade, and these exceed the consideration of analytical uncertainty, it is suggested that economies communicate with each other prior to taking any

⁸ United States Food and Drug Administration Compliance Program Guidance Manual (2011). Program 7304.004, Pesticides and Industrial Chemicals in Domestic and Imported Foods.

enforcement action. This will enhance the ability of goods to flow throughout the international marketplace.

[FIVS](#) is an international federation serving trade associations and companies in the alcohol beverage industry from around the world. It provides a forum for its members to work collaboratively on legal and policy issues and communicates Federation views to national governments and international organizations.