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The Purpose of Certificates of Analysis

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The Purpose of Certificates of Analysis

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Overview

- Introduction
- Is there a need for Certificates of Analysis?
- Some considerations where it is decided to require certificates
- The APEC WRF initiative

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When the APEC WRF began...

- One aim to reduce the costs of unnecessary testing and certification in the region (estimated at 1 billion USD per annum).
 - Significant progress made on export certification and on harmonization in the case of agrochemical MRLs
 - Facilitated access to regulations in the region through FIVS-Abridge
 - Certificates of Analysis (CoAs) seem to offer another opportunity

Certificates of Analysis

- Each economy may have different requirements
- Perhaps even difference requirements at different ports of entry
- Not always simple to establish what analyses are required for each destination economy
- Sometimes the reasons for which certain analyses are requested are unclear
- Sometimes the definition of terms used on CoAs is different or unclear (e.g., “sugar” means different things in different places)
- Sometimes the requirements in terms of acceptable analysts/laboratories are different
- All this lack of clarity and the differences between economies creates uncertainty and unnecessary costs for governments and producers.

Why Certificates of Analysis?

- Often said to be related to:
 - Public health and safety matters
 - Demonstrating compliance with local regulatory or commercial requirements
- This paper will examine whether CoAs actually serve a public health requirement. The aim is:
 - To consider possible elimination of CoAs for wine in the APEC region, or else:
 - In the short term, to greatly simplify and harmonize analysis requirements on CoAs for those economies that wish to keep such a certificate for wine.

36 analytes that are sometimes requested on Certificates of Analysis in different parts of the world.

Appearance	Hybrids	Stability at -5°C
Bacteria, cultured	Iron	Sucrose
Calories	Lead	Sugar Free Extract
Citric Acid	Limpidity	Titratable 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

Analytes on Certificates of Analysis by Groups

- “Health and Safety”
- “Wine Quality and Legality”
- “Additive Levels”
- “Microbiological”
- “Physical Characteristics”
- “Typical Wine Parameters”

“Health and Safety Analytes”

- **Sulphur Dioxide**
 - Levels in wine are too low to cause problems for most people
 - At levels that could be a concern, the product would be unpalatable
 - For susceptible individuals, a sulphite indication is given on the product label
- **Methanol**
 - Often considered a health problem but as the paper presented in Ottawa shows, this is not the case at the levels typically present in wine made according to Good Oenological Practices (GOP).
- **Heavy Metals**
 - Typical levels found in wine produced according to GOP and consumed in typical quantities do not cause intakes that exceed JECFA acceptable levels.

“Wine Quality and Legality” Analytes

- Ethanol, gas pressure
 - May classify wines with regard to their legal status (i.e., tax class). May be addressed in other accompanying documentation.
- Methanol, volatile acidity
 - May provide a rough indication of the care taken during winemaking, storage, and bottling.
- None of these poses a health concern at levels typically found in wine produced according to GOP.

“Additive Levels” Analytes

- 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.

“Microbiological” Analytes

- Pathogens: *Salmonella*, *E. Coli*
 - As we have seen, due its low pH, alcohol, polyphenol and sulphite content, low redox potential etc., no pathogenic microorganisms are able to survive in wine.
- Yeasts
 - Yeasts used in wine production and/or subsequently found in wine do not represent any health and safety concern.

“Physical Characteristics” Analytes

- Include appearance, colour, limpidity (clarity), and stability.
- Not related to health and safety impacts but are subjective descriptors of wine characteristics.
- Subject to changing consumer interests, so their use in a regulatory capacity is questionable. They could also create barriers to trade as they have the potential to impact traditional wine styles from some regions.

“Typical Wine Parameters” Analytes

- These include pH, sugars, density, acidity, etc.
- Since wine is made from natural grapes, the values for these parameters typically fall within a narrow range, unrelated 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 these reasons, these parameters should be excluded from any testing related to health and safety.

Overall Rationale for Certificates of Analysis

- In summary, the test parameters collated from CoAs in markets around the world are either:
 - not related to public health and safety, or
 - very unlikely to reach harmful levels in wines produced according to good oenological practices.
- Analyses required for a CoA would thus have to be related to local regulatory or commercial requirements
- 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 accompanying documentation.
- The conclusion to this study of analytes requested on Certificates of Analysis for wine would therefore be that, from the perspective of product safety, there is no need for certificates of analysis for international wine trade.

When certificates of analysis are required...

1. The specific analyte required should be precisely defined.
For example, does “sugar” mean:
 - 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?
2. Analysis performed by internationally accredited laboratories (e.g. ISO 17025) whether of producers, governments or 3rd party laboratories, should gain wide acceptance.
3. Measurement uncertainty should be specified by laboratories and taken into account (as recommended within Codex Alimentarius)

APEC WRF Initiative

- In keeping with the aims and objectives of the WRF, this seemed like a useful area for an initiative with the following goals:
 - To identify the current requirements for Certificates of Analysis among APEC economies
 - To consider the precise purpose these serve and whether they are essential
 - To contemplate a simplification by the elimination of Certificates of Analysis altogether or some progress towards harmonization for those economies where that may not be possible

APEC WRF Initiative (cont.)

- Accordingly, economies received a survey sheet on this subject on April 28, with a request to complete the following table:

1. Does your economy require certificates of analysis for importation of wine?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
2. If yes, which of the following analytes are required:		
Alcohol by Volume	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Total Extract	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Total Acidity expressed as tartaric acid	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Volatile Acidity	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Residual Sugars, expressed as glucose + fructose	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Total Sulfur Dioxide	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Sorbic Acid (Sorbate)	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Methanol	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Other _____	<input type="checkbox"/> YES	<input type="checkbox"/> NO

APEC WRF Initiative (cont.)

- The Compendium Working Group will Collate the responses received
- **Thank you** to all the economies which have already submitted information!
- If your economy has not yet responded, please do!
- The data will be handed to the Export Certificate Working Group for consideration
- The aim is to review the results and consider potential actions at the meeting in 2018.

Thank You!
