Regulatory Principles to Enhance Coherence and Facilitate Trade in Wine – Part 2

1 Executive Summary

Following the production and endorsement by FIVS of the original 12 principles on establishing regulatory limits for wine and testing for compliance by analysis, and as anticipated at the time, several additional principles have been identified and are explained and advanced in this paper. As with the previous set, implementation of these new tenets would seem to bring significant benefits in international trade in wine, without diminishing consumer protections or other damage to other policy objectives.

The following are the additional principles covered in this paper:

- In the absence of specific limits for a particular substance in wine, Governments should not apply limits developed for other foods or beverages with different background levels of the substance, production considerations and intake data.
- Enforcement activity should not normally be taken on the basis that a wine contains a non-harmful substance at levels which reflect the naturally occurring levels found in wines from the same origin, produced in accordance with good oenological practices.
- Enforcement activity should not normally be taken on the basis that a wine contains an adventitious substance at levels consistent with production in accordance with good oenological practices, and lower than relevant limits established from a public health perspective by suitably qualified experts.
- Where appropriate, permit the reporting of an analytical result as being below the limit of detection for a method (e.g. <0.05 mg/L), without interpreting this as indicating some presence of the substance in wine so as to trigger a labeling or other regulatory requirement.
- The usage level of winemaking treatment agents permitted for wines traded internationally should usually be according to GMP (Good Manufacturing Practice) where the Joint Expert Committee on Food Additives (JECFA) has set an Acceptable Daily Intake of "Not specified" (meaning there are no known health concerns with the substance). Numerical usage limits should be science-based and established with reference to the recommendations of appropriate international intergovernmental organisations (e.g. Codex Alimentarius Commission, OIV) and should not be more restrictive than these recommendations
- Specify and agree upon a method for referring to winemaking treatment substances in regulations that minimizes or eliminates the possibility of confusion due to the existence of synonyms for those substances.

- Those winemaking treatment agents that are naturally present in grapes and/or wine, are actually derived from these sources, and that are used in winemaking solely to adjust the levels of the same substances already present in grape juice or wine, should not be required to be indicated on the label of the resulting product.
- Exempt standard wine from expiration date labeling, in the light of product characteristics.
- Regulators in exporting and importing countries should establish reliable means of communicating with one another, which should be used promptly when some form of enforcement activity is being contemplated for wine in international trade.

It is hoped that this second set of principles may be considered by the members of FIVS as an extension to the contents of the original 12 principles.

2 Introduction

This paper may be regarded as an Appendix to the earlier document, which advanced 12 Principles concerning good practice in the establishment of regulatory limits for wine and in subsequent testing of wines for compliance with those limits by analysis, and which was endorsed by the members of FIVS.

It has been stated many times that the original 12 principles only marked the beginning of the creation of a body of work on good regulatory practice for wine, the implementation of which seems likely to have significant, positive impacts on wine trade globally. Accordingly, this paper now presents an additional nine principles.

As with the original 12 principles, those presented here all have their origin in real-life, wine trade-distorting episodes, so their practical value is already demonstrated.

It is entirely likely that further principles will emerge over time, and will be gathered into collections of a size suitable to present to FIVS members for consideration, as in the current paper.

3 Principles relating to the levels of substances present in wine

3.1 Application to wine of public safety limits developed specifically for other foods and/or beverages

The limits developed to regulate the quantity of substances of public health concern that may be present in a given food are developed based on the consideration of several factors, including:

- a review of toxicological studies related to the substance;
- Information regarding the raw materials and production processes used in making the product;
- any known matrix effects related to the product itself; and
- data that shows the contribution that can be made to total dietary intake of the limited substance by known per capita consumption levels of the foods in which it may be present at the limited value.

It is consequently entirely inappropriate to apply the limit established for a given substance of concern in one specific product to a different product where many or most of the factors listed above are likely to be completely different.

In recent times, we have seen a tendency for this very practice to be undertaken. So, for example, the limits for certain heavy metals and certain residues from packaging materials that have been developed specifically for drinking water have been applied as though they must be appropriate for wine. It is obvious, though, that production practices, raw materials, possible matrix effects, and certainly the anticipated per capita consumption of water compared with those for wine are very significantly different, so that there can be no valid basis for applying drinking water limits to wine.

Accordingly, it seems appropriate to develop a generic principle that highlights this issue and discourages the practice.

Principle: In the absence of specific limits for a particular substance in wine, Governments should not apply limits developed for other foods or beverages with different background levels of the substance, production considerations and intake data.

3.2 Naturally occurring wine components present at typical levels

There has been a flurry of instances in recent months where wine has been impeded in international trade on the basis that it contains "excessive" amounts of a non-harmful substance. Upon investigation, the substance is found to be naturally occurring in wines from the producing country in question, and present in the samples under investigation at levels which are perfectly within the typical range of values seen. This increasingly frequent scenario gives rise to this principle:

Principle: Governments are respectfully invited to agree that enforcement activity should not normally be taken on the basis that a wine contains a non-harmful substance in amounts which reflect the naturally occurring levels found in wines from the same origin, produced in accordance with good oenological practices.

3.3 Adventitious substances present in wine at levels lower than relevant limits set by qualified experts

There have been several media reports and some enforcement actions in the last two years where substances not usually present in wine, but present as a result of production in keeping with good oenological practices, were found at levels well below limits set from a public health perspective in regulations and in recommendations developed by suitably qualified experts. In one case, many consignments of product were detained and not permitted to freely access the market while discussions to explain the technical aspects of the issue were pursued and much costly testing was undertaken.

Principle: Governments should not normally take enforcement action on the basis that a wine contains an adventitious substance at levels consistent with production in accordance with good oenological practices, and lower than relevant limits established from a public health perspective by suitably qualified experts.

3.4 Reporting results where no presence was detected by analysis

It is good analytical and laboratory practice to report results according to certain well-established conventions. According to one of these, when an analysis fails to detect the presence of the substance being determined, the result will be presented as below the limit of detection for the method used. So, for example, if a method has a limit of detection of 0.05 mg/L, the result would be expressed as <0.05 mg/L (i.e. below the limit of detection).

In certain markets, results expressed in this way are being interpreted as indicating that the substance being tested for is, in fact, present in the wine (because the result is not shown as 0.00 mg/L). Then demands are made (for example) for labels to be changed to indicate that the substance is in the wine, when the result actually says it cannot be detected with the method that was employed.

Principle: Where appropriate, Governments are respectfully requested to permit the reporting of an analytical result as being below the limit of detection for a method (e.g. <0.05 mg/L), without interpreting

this as indicating some presence of the substance in wine so as to trigger a labeling or other regulatory requirements.

4 Principles relating to winemaking practices

4.1 Levels of use for winemaking treatment agents

It is a principle established by the Codex Alimentarius Commission in regard to food additives in general that the usage level for an additive entered into the General Standard for Food Additives (GSFA) should be according to Good Manufacturing Practice (GMP) in the case of all agents for which the Joint Expert Committee on Food Additives (JECFA) has set an Acceptable Daily Intake of "Not specified" (meaning there are no known health concerns with the substance). This principle applies unless some compelling technical justification can be produced to do otherwise.

It is a well-accepted practice in relation to food regulation to establish general standards that apply to all goods traded internationally, while allowing governments to impose stricter provisions on their own producers if they choose to do so.

Accordingly, it would seem to facilitate trade significantly if governments were to agree that they would accept GMP usage levels in internationally traded wine for those additives where JECFA has set an Acceptable Daily Intake of "Not specified".

It is a matter of fact that there is a cost associated with every addition that is made in the course of the winemaking process, and it is also true that addition of too much of any given permitted substance will result in a product of less than optimal quality. For both these reasons, use of winemaking treatment agents is self-limiting in practice, so a GMP usage specification does not open the door to abuse. This is the experience of those countries that have chosen this path even for their domestic production. It is certainly possible for guidance to be supplied to winemakers in the case of specific treatments, indicating the approximate usage levels that might be used and may constitute good manufacturing practice in certain circumstances. This can be done through a code of practice document, for example.

Where numerical usage limits are implemented, these should be science-based and established with reference to the recommendations of appropriate international intergovernmental organisations (e.g. Codex Alimentarius Commission, OIV) and should not be more restrictive than these recommendations.

Principle: Governments are respectfully requested to agree that the usage level of winemaking treatment agents permitted for wines traded internationally should usually be according to GMP (Good Manufacturing Practice) where the Joint Expert Committee on Food Additives (JECFA) has set an Acceptable Daily Intake of "Not specified" (meaning there are no known health concerns with the substance). Numerical usage limits should be science-based and established with reference to the recommendations of appropriate international intergovernmental organisations (e.g. Codex Alimentarius Commission, OIV) and should not be more restrictive than these recommendations

4.2 Nomenclature of substances used in winemaking treatments

Many of the substances used in winemaking treatments are known by multiple different names around the world. The table below illustrates this fact, but is far from comprehensive:

Substance	Synonym(s)
Dimethyl dicarbonate (DMDC)	Dimethyl pyrocarbonate (DMPC)
Potassium bicarbonate	Potassium hydrogen carbonate
Potassium bitartrate	Potassium hydrogen tartrate
Gum Arabic	Acacia
Silicon Dioxide	Silica
Copper sulfate (sulphate)	Cupric sulfate (sulphate)
Ascorbic Acid	Vitamin C
Erythorbic Acid	Isoascorbic Acid
PVPP/PVI polymer	PVI/PVP co-polymer, Divergan HM

The potential for confusion in the interpretation, application and enforcement of winemaking regulations is very clear, and some mechanism for clarifying which substance is meant would remove the potential for inadvertent trade barriers. Two possibilities have been suggested, but there may be other approaches:

1) Along with the substance specified in regulations by one or more of its synonyms, give the unique CAS Registry number for the substance (Chemical Abstracts Service). This number doesn't change, regardless of the synonym that is used. Those substances not having a CAS number are probably themselves food substances not likely to be confused in regulatory entries. The International Numbering System (INS) may also be used.
2) Probably more difficult would be to produce a list of approved winemaking substances and specify which synonym will be used in winemaking regulations by convention.

Principle: Governments are respectfully requested to specify and agree upon a method for referring to winemaking treatment substances in regulations that minimizes or eliminates the possibility of confusion due to the existence of synonyms for those substances.

4.3 Natural grape components used as winemaking treatment agents

The uniqueness of wine as a food is well documented, and gave rise to some of the principles in the first paper on this subject. Indeed, because of its characteristics, wine is often regarded as a "single ingredient food" in many regulatory frameworks internationally. One of the ways this manifests itself is in the production of wine. The vast majority of substances that are used in winemaking naturally occur in grapes or wine, and are used solely to adjust the levels of the same substances already present in grape juice or wine. They are added to bring components such as sugar or acid into balance. In most cases, their addition is not necessary in order to arrive at a product meeting the definition of wine, but it is absolutely essential to produce a product that is optimal in balance and appealing to the consumer.

Nothing new is present in the final product because of the addition of these substances, and no test can be conducted to show that the addition has taken place. Accordingly, significant scope for confusion and trade difficulties are created in markets where their addition is required to be declared on the label. This possibility is recognized in the OIV's "International Standard for the Labelling of Wines" (2015 edition),

Section 2.3 (Information on Additives) which recommends that information should only be mandatory on the label for those *additives that are not present in wine in its natural state in significant amounts*.

There are also situations in which a requirement to declare the addition can actually penalize honest traders.

For all these reasons, it seems appropriate to recognize that such substances, when used in winemaking, should not be required to be indicated on the product label.

Principle: Governments are respectfully invited to agree that those winemaking treatment agents that are "natural components" of grapes, are actually derived from grapes, and that are used in winemaking solely to adjust the levels of the same substances already present in grape juice or wine, should not be required to be indicated on the label of the resulting product.

5 Exemption from Expiration Date Labeling

Other characteristics of bottled wine that set it apart from many foods are its microbiological stability, and its ability to last for long periods of time in the market, and even to improve in quality and complexity over time. There are some very old bottled wines that are highly prized today! For these reasons, it is not appropriate to require that standard bottled wine should be labeled with "best before", "use by" or other such expiration date labeling terms.

Principle: Governments are respectfully requested to agree that standard bottled wine should be exempted from expiration date labeling, in the light of the product's intrinsic characteristics.

6 Communication between Wine Regulators in cases where enforcement action is contemplated

Much of the disruption to international wine trade could be avoided if the appropriate authorities in exporting and importing countries had well-established means of communication, and used them when enforcement action was being contemplated. This would give opportunity to clear up misunderstandings and present necessary information before costly episodes commence in earnest.

Principle: Governments are respectfully requested to agree that regulators in exporting and importing countries should establish reliable means of communicating with one another, and that these should be used promptly when some form of enforcement activity is being contemplated for wine in international trade.

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.