ANNEX: GOOD MANUFACTURING PRACTICES IN PRACTICAL TERMS

Drawing upon the Codex Alimentarius Commission[1] definition of "Good Manufacturing Practice" (GMP) and the points outlined in the foregoing paper, "Regulating Winemaking Practice Additions in a Rapidly Evolving Global Market"[2] practical actions are outlined below for both producers and enforcers. These suggestions are intended to provide guidance for implementing a GMP approach to using and regulating approved winemaking additions in order to benefit from the advantages outlined earlier.

GMP IN GENERAL

The following table shows that there is a level of international familiarity with the concept of GMP. Several countries and regions have chosen in their general food regulations, for certain additives, to follow the approach adopted by Codex Alimentarius in its General Standard for Food Additives by specifying GMP as the usage limit where no established food safety risk exists.

Table: Countries/Regions/Organisations which use a GMP approach in food regulation (not exhaustive)

COUNTRY	LEGISLATION
AUSTRALIA	Australia New Zealand Food Standards Code - Standard 1.3.1 - Food Additives
CANADA	Food and Drug Regulations (C.R.C., C. 870), C.02.001.
EUROPEAN UNION	Regulation (Ec) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives
NEW ZEALAND	Australia New Zealand Food Standards Code - Standard 1.3.1 - Food Additives
SOUTH AFRICA	Foodstuffs, Cosmetics And Disinfectants Act, 1972
UNITED STATES OF AMERICA	21 CFR §24.110 Current good manufacturing practice in manufacturing, packing or holding human food

Notwithstanding this observation, this paper will now consider GMP only in the context of the usage level of winemaking additions, permitted under the appropriate regulations, in the course of crafting a wine.

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[1] *Codex Alimentarius International Food Standards Procedural Manual*, 22nd ed, Joint FAO/WHO Food Standards Organization of the United Nations. Rome, 2014, ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual_22e.pdf.

[2] *Regulating Winemaking Practice Additions in a Rapidly Evolving Global Market*, FIVS. Paris, 2014, https://fivs.org/public/download/document/1988/FIVS_Wine_Additives_Paper_Regulating_Winemaking_Practice_Additions_in_a_Rapidly_Evolving_Global_Market_20141127.pdf.

GMP FOR PRODUCERS

Good manufacturing practice in the case of approved winemaking additions is defined as using the minimum amount possible in order to achieve a desired result. This approach is only feasible where a body such as the FAO/WHO Joint Expert Committee on Food Additives (JECFA) has determined there are no public safety concerns with the use of the substance at any reasonable level, and competent authorities have approved the substance for usage in wine. In these circumstances, the burden falls upon the producer to determine the following:

- Is a winemaking addition truly necessary?
- Is it a permissible addition in the wine's intended market?
- What is the minimum addition that can be made to accomplish the desired result?

In making these determinations, winemakers will need to bear in mind the constraints of cost and quality that apply with any treatment in winemaking, including:

- *Wine identity:* oenological practices have been developed for adjusting the natural characteristics of the product and to enhance the balance in which the quality of a wine is based; not to transform the nature of the wine.
- *Wine stability:* oenological practices, and the use of additives in the production of wine shall be focused on maintaining the natural balance of a certain wine. It shall accompany the wine in its natural evolution
- *Consumer preference*: treatment will be established based upon the style of the product that is being crafted, its intended consumers, approximate tier in the market (e.g. premium, value, economy etc.) and the regulatory requirements in the intended market(s).
- *Cost*: excessive and costly treatment(s) with one or more substances will quickly render the product uncompetitive in the marketplace.
- *Possible negative effects*: due to the unique characteristics of wine as a product, each time a given wine is "touched" or treated there exists the potential for deleterious quality impacts. Such interventions should be kept to a minimum as excessive use of any winemaking practice will inevitably lead to a product that is less palatable and possibly even unsaleable.

Once the winemaker has determined that a treatment is indeed necessary, the next task will be to determine what represents the minimum level of addition that will accomplish the desired endpoint. In practice, in order to establish this, one or more bench-scale trials may be performed, followed by sensory or other evaluations, before scaling up the treatment to the wine in production.

DUE DILIGENCE

The concept of due diligence has been recognized by several governments and international regulatory bodies across a range of industries. It entails the producer being able to demonstrate that they took all reasonable steps and exercised all due diligence in their processes to be compliant with relevant standards and regulations and to produce safe and wholesome products.

Hence, the principle of "reasonableness" is applied in establishing due diligence systems. This is because the systems implemented should be those which are "reasonable" to expect from a given producer in a certain set of circumstances (for example, size and location). Such an approach may entail the implementation of a documentation system (if it is not already in existence) that will enable key aspects of the use of winemaking additions to be recorded including:

- Date and time of treatment
- Suitability, specifying that only authorized treatments were performed, and for their intended purpose(s)
- Quality, assuring that added substances are of food grade and conform to the applicable Specifications of Identity and Purity developed by competent international or national bodies (for example, the Codex Alimentarius Commission[3] or the International Organisation of the Vine and Wine (OIV), and stored in a suitable manner prior to use.
- Quantity, confirming the amount of substance used, manner of use (where appropriate) and the volume of wine that was treated.
- Traceability, identifying batch numbers of substances should be part of the specific wine's treatment history.
- Execution, ensuring treatments are carried out by appropriately qualified individuals and only to the minimum extent necessary, as established beforehand by bench scale trials (if appropriate).
- Follow up, detailing appropriate analytical parameters that indicate the treatment achieved the desired outcome

Records such as these will also be valuable in traceability investigations where those may prove necessary.

In practice, all these considerations and more are included in well-known food quality/safety management systems such as ISO 22000[4].

GMP FOR ENFORCERS

There may be benefits to competent authorities when regulations specify "GMP" as the usage level for certain approved winemaking adjustments where there is no public safety risk. Nevertheless, if the authorities in a given country or region determine in such a case that it is appropriate to establish numerical limits for usage, such limits should be science-based. They should also be set with reference to the recommendations of appropriate international intergovernmental organisations (e.g. Codex Alimentarius and OIV) and may in no case be more restrictive than these recommendations, so that the international trade of wine is not disturbed.

[3] CODEX STAN 192-1995, Codex General Standard for Food Additives (GSFA). Geneva, 2015, http://www.codexalimentarius.org/standards/gsfa/.
[4] International Organization for Standardization (ISO), 22000:2005 Food Safety Management. 2009 http://www.iso.org/iso/home/standards/management-standards/iso22000.htm

Competent authorities should also be familiar with the concept of due diligence, so that they take into account the size and circumstances of a producer in determining what may constitute reasonable production management measures.

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.