Risk Based Limit Setting Guidelines

1. Summary

Consumer protection sits at the heart of regulatory controls over production, compositional requirements, product representations, trade practices and intellectual property concerns, but also provides the foundation for a functional and growing wine trade sector that operates with integrity.

Internationally accepted principles in Regulatory Best Practice lay down criteria for ensuring that any regulatory intervention to enhance consumer protection through limit-setting are evidence-based, cost effective, transparent, targeted and operate proportionately under the most appropriate models, including self-regulation and co-regulation.

The ideal is to prevent any arbitrary or unjustifiably discriminatory measure between trading partners where identical or similar conditions prevail. Most important is the objective to prevent preparation, adoption or application of regulatory measures that, unintentionally or otherwise, have the effect of creating unnecessary obstacles to international trade.

It is recommended to integrate in this process the consideration of the recommendations of the Organisation of Vine and Wine (OIV)[1] or other international intergovernmental organisations with recognised expertise in the field of vitiviniculture.

2. Why Are Limits Set In Regulation?

In 1538, the alchemist and physician Philippus Aureolus Theophrastus Bombastus von Hohenheim, also known as Paracelsus wrote, “Alle Dinge sind Gift, und nichts ist ohne Gift, allein die Dosis macht dass ein Ding kein Gift ist.”, which translates to English as “All things are poison, and nothing is without poison, the dosage alone makes it so a thing is not a poison.” Paracelsus is considered to be the father of toxicology and this particular writing has inspired a shortened phrase for use in modern times conveying the idea that “The dose makes the poison.” It also marks, perhaps for the first time, the clear articulation of an overt concern about the principles of product safety and consumer protection.

Consumer protection sits at the core of most international legislation that relates to product health and safety, guarantees to prevent false and misleading representations to the consumer and product fitness for purpose.

[1] OIV: Organisation Internationale de la Vigne et du Vin (International Organisation of Vine and Wine) – is an intergovernmental organisation of a scientific and technical nature of recognised competence for its works concerning vines, wine, wine-based beverages, table grapes, raisins and other vine-based products.

From a specifically 'Health and Safety' point of view, limits established within legislation for wine cover elements such as contamination, chemical residues and appropriate use of ingredients, thereby regulate the way wine is made, what it contains, how it is blended, what test(s) it needs to pass, and whether any warnings or representations are required on the label. These limits may also be established to *prevent the modification of the natural and essential characteristics of the wine and a substantial change in the composition of the wine.*

The consumer guarantee that the wine in the bottle will match any description on the label or elsewhere goes to the heart of 'Authenticity' and is governed by labelling rules that dictate claims of vintage, grape variety, geographical representations and country of origin.

Fit for purpose, the guarantee that a wine is of acceptable 'Quality' draws from obligations that the wine is true to its presentation, acceptable in appearance and taste, free from defects to packaging or contents, safe to consumer and durable and maintains its *natural and essential characteristics*. Quality is, and should be, flexible with regard to systems employed to achieve control over limits and compositional control, utilising a combination of regulatory (government audited) and self-regulatory (internal and independent third party audited) strategies.

3. Using Best Practice Regulation Principles

Additionally, when deciding the compositional criteria within a regulation that governs market entry for either domestic or imported food, it is important to address three key criteria; *Rationale*, *Relevance* and *Risk*.

Rationale: What is it about an individual regulatory limit that requires control due to potential effects on human health or as a proxy marker for "Quality" or "Authenticity" as described previously? Is there an immediate crisis, an arising scientific consensus or a demonstrated market failure?

Relevance: How does the proposed controlled limit feature within the category of wine in relation to wine? Is it of environmental origin? Does it arise as a result of agricultural processing? Is it an important concern arising in manufacture either intentionally or unintentionally? Is it in line with the recommendations of the OIV or other international intergovernmental organisations with recognised expertise in the field of vitiviniculture?

Risk: Assuming there is both a justified Rationale and demonstrated Relevance to a wine, what interventions are best implemented to reduce the Risk to a minimum effective threshold that directly addresses the Rationale? Is that elimination, or limitation? Can it be addressed in the agricultural production environment? Can you utilise changes or interventions in production methods? Is it already addressed in codes of practice or national guidelines?

As development of regulations has been considered, progressive governmental bodies have begun to consider the regulatory process. They have examined how regulations are written, why they are written, how they might affect those who must comply with those regulations. The result of one such examination is known as the principles of "Better Regulation". Five principles were identified and serve as basic tests for determining whether or not a regulation is fit for purpose:

> **Proportionality -** Regulators should intervene only when necessary. Remedies should be appropriate to the risk posed, and costs identified and minimised.
>
> **Accountability -** Regulators should be able to justify decisions and be subject to public scrutiny.
>
> **Consistency -** Government rules and standards must be joined up and implemented fairly. They should not be more restrictive than the recommendations established by relevant international intergovernmental organisations.
>
> **Transparency -** Regulators should be open, and keep regulations simple and user-friendly.
>
> **Targeting -** Regulation should be focused on the problem and minimise side effects.[2]

These principles are similarly reflected by the Organisation for Economic Co-operation and Development (OECD) in their "*Recommendation of the Council on Regulatory Policy and Governance (2012)*[3]*".* Contained within the 12 OECD Recommendations are the following key principles of relevance to limit setting:

- The policy should have clear objectives and frameworks for implementation to ensure that, if regulation is used, the economic, social and environmental benefits justify the costs, distributional effects are considered and the net benefits are maximised.

- Regulation serves the public interest and is informed by the legitimate needs of those interested in and affected by regulation.

- Integrate Regulatory Impact Assessment (RIA) into the early stages of the policy process for the formulation of new regulatory proposals. Clearly identify policy goals, and evaluate if regulation is necessary and how it can be most effective and efficient in achieving those goals. Consider means other than regulation and identify the trade-offs of the different approaches analysed to identify the best approach.

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[2] U.K. Better Regulation Task Force, *Principals of Good Regulation,* http://webarchive.nationalarchives.gov.uk/20100407173247/http://archive.cabinetoffice.gov.uk/brc/upload/assets/www.brc.gov.uk/principlesleaflet.pdf, sourced 25/03/2018.

[3] OECD, *Recommendation of the Council on Regulatory Policy and Governance*, http://www.oecd.org/governance/regulatory-policy/49990817.pdf, sourced 20/04/2018

- In developing regulatory measures, give consideration to all relevant international standards and frameworks for co-operation in the same field and, where appropriate, their likely effects on parties outside the jurisdiction.

The key issue to be understood here is that regulatory policy directing Risk Management for a food category should not entail legislative restrictions, limits to production methods or spurious analytical screening demands that do not address a justifiable and demonstrated consumer risk issue, and especially not one for which the regulated food in question has no evidentiary history of being a contributing factor to the issue.

4. Best Practice Regulatory Principles In Trade

The World Trade Organisation (WTO) articulates the principles of Best Practice Regulation in the Agreement on the Application of Sanitary and Phytosanitary Measures in Article 2 Basic Rights & Obligations, parts 2 and 3 respectively

> *Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence,*
>
> *Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.*[4]

Furthermore, the WTO also enunciates clearly within its Agreement of Technical Barriers to Trade in Article 2 Preparation, Adoption and Application of Technical Regulations by Central Government Bodies, sections 2.2 and 2.3 respectively:

> *2.2 Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create.*
>
> *2.3 Technical regulations shall not be maintained if the circumstances or objectives giving rise to their adoption no longer exist or if the changed circumstances or objectives can be addressed in a less trade-restrictive manner.*[5]

[4] The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm, sourced 20/04/2018
[5] The WTO Agreement on Technical Barriers to Trade, https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm, sourced 20/04/2018

These Agreements form the bedrock for a set of trade principles adopted by the World Wine Trade Group (WWTG), which are collectively known as the Tbilisi Statement, as they were agreed upon at their 2014 meeting in Tbilisi, Georgia. A nearly identical set of these principles has been endorsed by FIVS, a worldwide organisation representing the alcohol beverage industry.

This paper addresses the implementation of Tbilisi Principle #01: **Avoiding unnecessary analyses**

> *"Governments should establish regulatory limits that are based on risk, thereby avoiding unnecessary analyses."*

If then, there is not a demonstrable reason for setting of limits, any which are imposed would only serve to create a de facto trade barrier. Wine is one of the most widely traded commodities throughout the world, and in this era of global trade, it is imperative that trade is allowed to occur freely and without unnecessary barriers. Indeed, to introduce such hindrances would go against all that the cooperative efforts of groups such as the WTO, Codex Alimentarius and WWTG (in its Tbilisi Statement) have achieved. Such limits, when more restrictive than the recommendations adopted by relevant international intergovernmental organisations, restrict trade or increase costs to both the producer and the consumer without offering any additional protection or product safety.

4.1 Health and Safety Parameters of Wine

Effective and efficient interventions such as good agricultural practices, good oenological practices, the preservation of natural and essential characteristics of the wine, national drinking guidelines and nationally relevant consumer data about daily consumption patterns will be key considerations in risk mitigation and limit setting. Additionally the guidance of recognised international toxicological evaluation from forums such as the Joint Expert Committee on Food Additives (JECFA)[6] must be considered.

As an example, 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 exceed levels of toxicological concern.

Additionally, although methanol is considered a substance of concern for some beverages,

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

the levels found in wine are well below those presenting issues related to health[7].

4.2 Relevance of Wine Legality Parameters

Limits are sometimes applied in order to define the product's legal status (i.e., tax class), declared wine type (by sweetness, carbonation status or table wine/fortified wine status where controlled in certain markets) or preserve the natural and essential characteristics of the wine. These limits do not pose standalone consumer risk concerns (outside of dietary alcohol intake limits for ethanol), and should not be subjected to arbitrary limit setting.

4.3 Relevance of Additive Levels

Wine additive levels, which include substances such as sorbic acid, citric acid and copper, merely indicate how much of a given permissible additive was used during production. When used according to Good Manufacturing Practices (GMP) (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 consumer risk, given typical consumption levels and the wide margin of toxicological safety and must prevent (i) the modification of the natural and essential characteristics of the wine and (ii) a substantial change in the composition of the wine. Similarly, they should not be subjected to arbitrary limit setting based on technological application only and, if further specified, should be set with reference to the recommendations of the OIV or other international intergovernmental organisations with recognised expertise in the field of vitiviniculture.

4.4 Relevance of Microbiological Criteria

The microbiological category, which includes bacteria, yeast, and fungi, is in no way a consumer risk concern for wine. It should be noted that yeast is actually scientifically classified as a fungus, so in reality, these two are functionally the same.

Due to the low pH, alcohol, polyphenol and sulphite content of wine, no pathogenic microorganisms are able to survive in it. This topic is dealt with in detail in the FIVS discussion paper *Microbiologically, Wine is a Low Food Safety Risk Consumer Product.*[8]

4.5 Relevance of Physical Characteristics

Physical characteristics include criteria such as appearance, colour, limpidity (clarity) and stability. None of these are related to consumer risk and should not be subjected to arbitrary limit setting.

4.6 Relevance of Typical Wine Parameters

Many economies require the testing of basic wine parameters for import of wine. These include such tests as pH, sugars, density, acidity, etc. Since wine is made from natural grapes,

[7] FIVS (2016), *Methanol in Wine*. Paris, France

[8] Microbiologically, Wine is a Low Food Safety Risk Consumer Product, http://www.oiv2016.org.br/anais-do-congresso/_source/resumos/04203_2016-1236.pdf

these parameters typically fall within a narrow range of values, none of which is related to consumers' health risk. For this reason, these parameters can be excluded from any limit setting related to consumers' health risk and should not be subjected to arbitrary limit setting.

5. Wine Production Risk Management as a Regulatory Intervention

The first line intervention to be considered in addressing any valid consumer risk with demonstrated relevance to wine production, is the application of GMP and Best Practice principles for maintenance of Food Hygiene within national legislation. Upon this foundation a proactive strategy may be employed utilising the principles of Hazard Analysis & Critical Control Point (HACCP). This approach is already a worldwide-recognised systematic and preventive approach that addresses biological, chemical and physical hazards through anticipation and prevention, **rather than through end-product inspection and testing**.

The revised *Recommended International Code of Practice - General Principles of Food Hygiene* [CAC/RCP 1-1969, Rev 3 (1997)] was adopted by the Codex Alimentarius Commission during its twenty-second session in June 1997. The *Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application* is included as its Annex.

5.2 Risk Management of Additives

National regulatory authorities typically apply strict criteria to the safety assessment of food additives, namely:

- There is a good technological reason for using the additive.
- The food additive is safe at the limits it may be utilised for achieving the technological outcome.

This is derived from the Codex General Standard for Food Additives where *"the use of food additives is justified only when such use has an advantage, does not present an appreciable health risk to consumers, does not mislead the consumer, and serves one or more technological functions. The quantity of a food additive added to food shall be limited to the lowest level necessary to achieve the intended technical effect, according to the basic principle of the Good Manufacturing Practice (GMP)."*[9]

Under Codex principles, the first step in the consideration of the safety assessment of food additives is an evaluation by a competent authority, including the establishment of an Acceptable Daily Intake (ADI) where relevant, and the elaboration of their identity and purity criteria. The ADI is an estimate of the amount of a food additive in food or beverages expressed on a body weight (bw) basis that can be ingested daily over a lifetime without appreciable health risk to the consumer.

[9] General Standard for Food Additives Codex Standard 192-1995 Revised 2016, http://www.fao.org/gsfaonline/docs/CXS_192e.pdf

It is worthwhile also citing here that according to JECFA, an ADI of "not specified" is a term applicable to a food additive of very low toxicity that *"…on the basis of available data (chemical, biochemical, toxicological, and other), the total daily intake of the substance, arising from use at the levels necessary to achieve the desired effect and from its acceptable background in food, does not, in the opinion of JECFA, represent a hazard to health."*[10]

The second step, the endorsement of the proposed use by relevant authorities, should take into account the ADI, or an equivalent health based guidance value, and the probable daily dietary exposure to the additive from all food sources. When the food additive is to be used in foods eaten by special groups of consumers (e.g., diabetics, those on special medical diets, sick individuals on formulated liquid diets), account shall be taken of the probable daily dietary exposure to the food additive by those consumers.

Importantly Codex states that where Maximum Limits (ML) are utilised it will necessarily overestimate the exposure to a food additive from its use in a given food. The MLs *"... will not usually correspond to the optimum, recommended, or typical level of use. Under GMP, the optimum, recommended, or typical use level will differ for each application of an additive and is dependent on the intended technical effect and the specific food in which the additive would be used, taking into account the type of raw material, food processing and post-manufacture storage, transport and handling by distributors, retailers, and consumers."*[11]

To this end, where an ADI is "not specified", or is not relevant or applicable, similarly so the utilisation of any limit setting other than acceptance of GMP and its inherent variability according to individual wine producer requirements is not an evidence based approach to limit setting under the *Codex Guidelines For The Simple Evaluation of Dietary Exposure to Food Additives CAC/GL 3-1 989 (Revised 2014).*[12]
In the particular case of wine, for the additives for which the Joint FAO/WHO Expert Committee on Food Additives (JECFA) has not established a numerical Acceptable Daily Intake (ADI) value:

- *The maximum level of the additive in grape wine set as Good Manufacturing Practice must prevent (i) the modification of the natural and essential characteristics of the wine and (ii) a substantial change in the composition of the wine;*
- *The maximum added level, if further specified, should be set with reference to the recommendations of the OIV or other international intergovernmental organisations with recognised expertise in the field of vitiviniculture.*

[10] Current Practices in the Codex Alimentarius Commission and Related Expert Committees, http://www.fao.org/docrep/008/ae922e/ae922e05.htm, sourced 20/04/2018
[11] General Standard for Food Additives Codex Standard 192-1995 Revised 2016, http://www.fao.org/gsfaonline/docs/CXS_192e.pdf
[12] http://www.fao.org/input/download/standards/6/cxg_003e.pdf, sourced 20/04/2018

6. Conclusions

Best Regulatory Practice is not solely a top-down endeavour where regulatory failure is the responsibility of government to identify and rectify. Within the international trade of wine there is a constant surveillance of inequalities in regulatory standard that are frequently presented in international combined government-industry forums such as the WWTG and the Asia-Pacific Economic Cooperation (APEC) Wine Regulators Forum.

The justification of regulatory intervention in consumers' health protection issues require a legitimate rationale of plausibility, applicability to the wine sector and quantifiable risk that would facilitate some form of regulation above "no regulation".

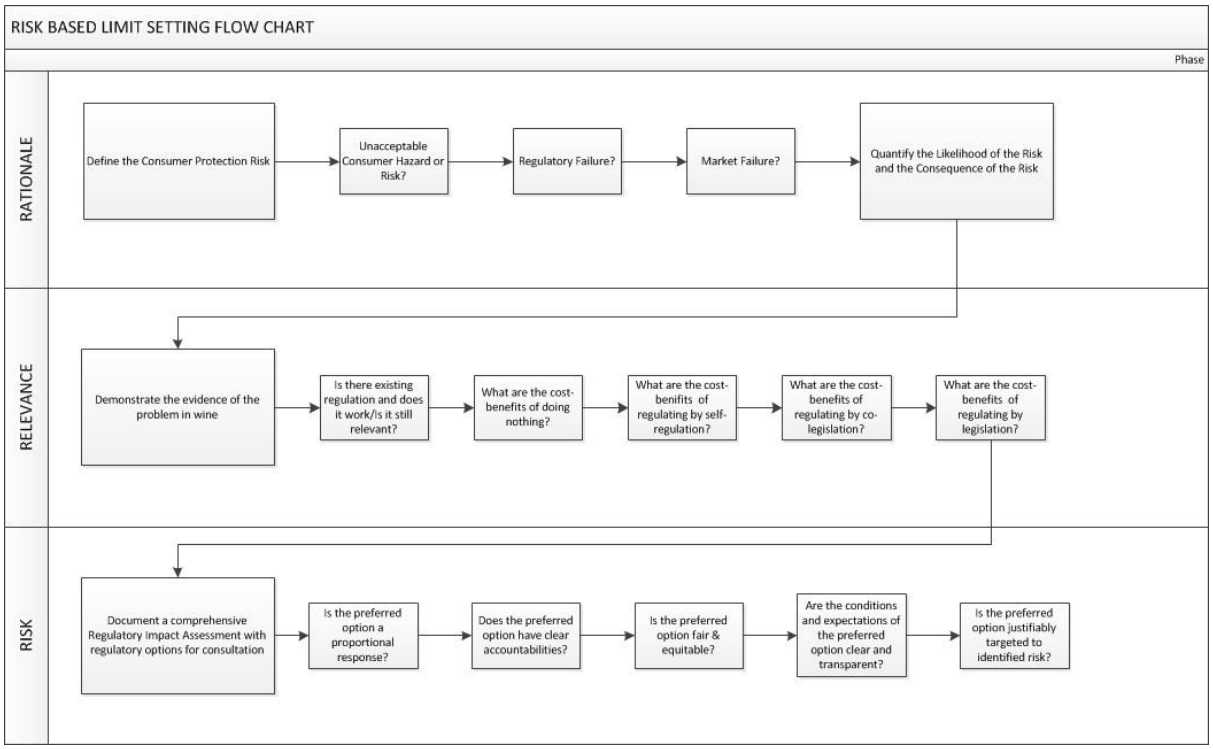
The characterisation of risk to consumers arising from issues of quality or authenticity similarly should not be undertaken in isolation from the extensive international data resources both industry and government can contribute outside the domain of sole national concern. Any possible limit should be set with reference to the recommendations of the OIV or other international intergovernmental organisations with recognised expertise in the field of vitiviniculture.

The application of Best Regulatory Practice also means a concerted examination of the regulatory structures in other trading partner markets for wine and determining the efficacy to mitigate real or perceived consumer risks for quality and authenticity. That application for a trading nation with existing controls also requires regular review of those regulatory framework to identify whether they continue to serve their intended purposes, or whether additional market conditions have removed the requirement for undue regulation.

Best Regulatory Practice in application of limits and controls to wine is therefore not a static exercise, but an ongoing exercise that requires both commitment and resources in order optimize trading efficiencies without compromising consumer protections.

Appendix

In order to facilitate the implementation of the principles enumerated in this paper, the following decision making flowchart is provided to the reader.



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.