

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of
the United Nations



World Health
Organization

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Agenda Item 5d

CRD 13
(Original language only)

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Forty-seventh Session

Xi'an, China, 17-21 March 2015

FOOD ADDITIVE PROVISIONS OF FOOD CATEGORY 14.2.3 "GRAPE WINES"

AND ITS SUB-CATEGORIES

(INFORMATION ON ACTUAL USE LEVELS AND RECOMMENDATIONS)

Comments of Kenya, African Union and Fédération internationale des vins et spiritueux (FIVS)

KENYA

Kenya agrees with recommendation 1 that ascorbic acid and gum Arabic is justified to be used for the purposes of antioxidants and stabilizers respectively.

We also accept recommendation 2 on the use of carbon dioxide on GMP as a carbonating, packaging and preservative for grape wines and its categories. In addition we support the amendment of the note with a maximum of use of carbon dioxide up to **4000 mg/kg** in still wine because beyond this level it will change the product from being still to sparkling wine.

We support the proposal by eWG to refer the pending issues to internationally recognized technical institutions. We propose the committee to adopt the referred organizations from which the data and information will be acceptable by the committee.

AFRICAN UNION (AU)

AU supports the agreements of the e-WG and proposes continuous dialogue and discussion due to the clear divergences of view on specific food additives. AU also supports the proposition regarding the involvement of OIV on provision of some information on the on-going evaluation of ten food additives used in wine-making

Rationale: By revising the food category and its sub-categories the descriptors and the technological justification of the emulsifier, stabilizer, thickener (EST) will be evaluated/re-evaluated. Some of these evaluations are underway. The collaboration with OIV should be extended to other sister international organisations.

FIVS

1. Introduction

Winemaking, and the use of substances in wine production, has occurred for thousands of years. Regulation, both in terms of what substances are allowed to be used, how they may be used, and how much may be used, is much more recent. Most typically, regulations have been drafted at a local or a national level. The factors considered in setting these regulations have sometimes been food safety concerns, but more often the basis has been the specific needs of wine production in that locality/country. The resulting regulations tend to be much more empirical than scientific in nature, but have prevailed until recently due to the relative lack of global trade in wine.

The rapid globalization of the market for wine has generally outpaced the revisions needed to national or regional wine regulations in a global market. Currently, there is a patchwork of different regulatory provisions in the various markets where wine is produced and sold, with little or no substantive scientific or other justification for the differences that exist. This has created a situation in which inadvertent technical trade barriers are rife, with many of them centered on differing usage levels for winemaking treatments.

For a large majority of the treatments performed in the course of winemaking, and involving the use of substances often referred to as food additives, there are no known public health concerns. Most involve the use of materials obtained from grapes to adjust the levels of the identical substances that are already present in the grape and its juice, to make a product that is optimized for consumer preferences. Levels of usage are self-regulating because of cost considerations on the one hand and the risk of making an unacceptable product on the other.

For the small proportion of substances used in wine production that are not naturally grape-derived, studies have been performed by JECFA and/or other organizations to determine if any health risks exist and if a maximum acceptable daily intake (ADI) of that additive needs to be established. This approach addresses any safety concerns that may exist.

Furthermore, since most additions are of grape-derived substances, it is impossible to determine by analysis how much has been added compared with the initial amount that was already present. This makes the enforcement of any limits of addition challenging if not infeasible in the context of international trade.

Finally, the effects of climate change are beginning to appear in winegrowing regions, and are expected over time to lead to changes in the quantities and types of the substances that might need to be used to make wine in a given region. In some circumstances, one might anticipate a decrease in the amounts used, but with the possibility of a concomitant increase for other treatments.

What is needed for sustained market growth in this situation is a more fundamental and harmonized approach to wine regulation relating to international trade (particularly in regard to winemaking practices) that will:

- Provide guarantees to consumers concerning the safety of the product
- Provide flexibility to producers to deal with rapidly changing circumstances
- Eradicate needless trade barriers globally and
- Reduce the burden of unnecessary and problematic enforcement activity on the part of the competent authorities.

This paper will consider each of these aspects, before identifying a possible way forward to resolve many of the challenges outlined above.

2. Maintaining Product Safety

From a food safety point of view, wine is acknowledged to be a low risk product. The typical levels of acid and alcohol in wine create an environment that does not support the growth of pathogenic organisms. Even when wine is stored poorly (leading to oxidation or transformation into vinegar), no significant risk to public health results.

As far as winemaking practices are concerned, many of the substances used to treat wine are themselves natural components of wine grapes (for instance, tartaric acid, grape must and related products, malic acid etc.), and they are used to adjust the levels that are already present in the unfinished product. For almost all these substances, scientific expert bodies such as the Joint Expert Committee on Food Additives (JECFA) are of the opinion that there is no known public health risk connected with their consumption.

Other treatment agents (and a small minority of those permitted in most winemaking countries) are not typically found in grapes. For some of these, JECFA has established a numerical Acceptable Daily Intake value (ADI), indicating that regulation of the amount we consume is appropriate.

What this means is that for the large majority of wine treatment substances that are permitted for use in winemaking, there are no safety concerns at all that might lead to a limitation in the amount used and therefore present in the finished product. For the small number of substances where a limit is appropriate, the ADI recommended by JECFA can be used to establish maximum levels and to ensure the safety of the end product. In practice, then, there should be no food safety concerns surrounding any given approach to the regulation of winemaking practices for international trade purposes.

3. Providing Flexibility

3.1 Producer Flexibility

In addition to ensuring product safety, the ideal regulatory framework for winemaking practice additions should provide as much flexibility to producers as possible, so that they can more easily adapt to the constantly changing circumstances that exist in a globalized market. Some of the current drivers that will require adaptations to winemaking practices include climate change, new developments in knowledge of winemaking, global market complexities, and consumer demands.

3.1.1 Climate Change

Wine production starts in the vineyard or orchard. Fruit (most often, grapes), can vary considerably in composition from region to region and may even vary significantly within single vineyards, due to microclimatic conditions (often referred to as “Terroir”). Fruit composition will also vary from year to year due to climatic conditions. The need for winemakers to intervene in all of these instances in order to produce wine with acceptable sensory characteristics from such highly variable raw materials has been recognized for centuries.

For example, cooler climate producers generally have more than enough acidity in their grapes, but will often need to add sugar (often from grapes) to obtain an appropriate final alcohol content and a sensory balance between the sugar and acid in the finished wine. Warmer climate producers, in contrast, seldom have problems getting sufficient sugar in their grapes for fermentation purposes, but their grapes can lack acidity, which will often need to be enhanced through an acid adjustment. In both these cases, the aim is to arrive at a finished product with a balance between sugar and acidity that will be acceptable to consumers and has an appropriate shelf-life. These production needs for wine are acknowledged in some markets with specific wine regulations, which allow additions of sugar (in various forms) and acids, and even make allowances for supplementary additions in years of exceptional climatic conditions.

While the extent of seasonal variations for a given region is generally well known, it is only relatively recently that climate change has emerged as a phenomenon that could radically alter the growing conditions in winegrowing regions. In some cases, winemaking practices will need to change in a somewhat unpredictable manner going forward. In other cases, regions that have not been viable centers of winegrowing may develop significant production capabilities but will need winemaking practice regimes adapted to the regional growing conditions.

Although the full scope, pace and extent of these changes are still largely unknown, they call for the most flexible possible regulatory approach for international trade, consistent with meeting policy objectives in respect of food safety and authenticity, while also meeting consumer expectations.

3.1.2 Developing Wine Knowledge

Our knowledge of wine, and of the applicability of winemaking practices, is continually evolving. Some practices that were once widely used are now almost unheard of, because superior treatments have been developed. In other cases, treatments that were originally developed for the treatment of white wines may be adapted to work well with reds. As scientific knowledge surrounding a certain practice develops, it may be deemed appropriate to increase the typical level of usage in order to optimize the outcome of the treatment in the light of new information, or even to adapt it to use with grape varieties of emerging consumer interest. Again, such considerations imply that a flexible regulatory system is much to be preferred in the context of international trade.

3.1.3 Global Market and Consumer Demands

Many national and regional regulatory provisions for winemaking were established before the wine market became the global entity that it is today. Producers in the 21st century need to be able to create stable, quality products that can endure disparate, lengthy, and often non-ideal supply chain conditions before reaching consumers. However, consumer expectations are not limited to the quality and safety of wines. They demand and search for new and innovative products in the marketplace; and these demands themselves often change rapidly, based on consumers’ perceived needs. The current growth of interest in lower alcohol wines and in organic wines represents just two manifestations of this phenomenon.

The ability to provide consumers globally with products that satisfy rapidly evolving demands is critical if the wine market is to continue growing. However, it is difficult or impossible where regulation of winemaking practices is very inconsistent internationally.

Changing regulations tends to be a relatively slow process, even within a single country or region. To change the recommendations applicable to the international trade that are produced by international, intergovernmental organizations often takes several years, even where the matter is given a high priority. Yet, as indicated above, the needs of a globalized market require a system of regulation that is much more adaptable than current systems yet can still fully meet imperatives of safety and consumer protection.

This discussion strongly suggests that it is not appropriate to set rigid and inflexible, numerical regulatory limits for winemaking practices where no public safety concerns attach to the substances employed. A better regulatory approach would apply an inherent and appropriate level of constraint to producers, while giving the necessary flexibility to meet the challenges outlined and still delivering necessary protections to consumers.

4. National Flexibility

Over the years, governmental administrations have created systems of regulation that are specific to their own producers, in order to develop and/or protect perceived advantages in the marketplace relating to quality, culture or heritage. Sometimes, because of the perceived status of products, (sometimes called luxury goods) the use of certain winemaking practices (for example, in the production of sparkling wines) can be used as the basis for national taxation policy. These programs can be implemented without the creation of trade barriers at the international level, and it is important that a global system of regulation for wine production allows flexibility at the national level for this sort of regulation to continue.

5. Eradicating Trade Barriers

It has already been stated that one purpose for a global approach to the regulation of winemaking practices is the elimination, as far as possible, of trade barriers for which there is no justification in terms of public health or other areas of consumer protection.

Winemaking practices have proven a particularly fertile ground for the emergence of trade barriers (often inadvertent) as the market has globalized and disparities between existing national and regional regulations have become apparent.

In a global market, to achieve maximum benefit from international trade, wine needs to move as freely as possible around the world with minimal uncertainty arising from unpredictable application of wine rules. Wine trade is hampered when consignments of wine may be delayed or even denied market entry while any perceived breaches of national winemaking regulations in the destination country are investigated. Where those rules do not relate to any meaningful public health or consumer protection risk or interest, the result is enormous cost without any benefits for the wine trade or consumers in the destination country. In addition, enforcement of such rules can divert regulators, whose resources are often stretched, from dealing with higher risk situations.

5.1 Unnecessary and Problematic Enforcement

There are many reasons why the establishment of inflexible, often numerical limits in connection with winemaking practices creates significant difficulties in terms of enforcement at the level of international trade. A few of these are detailed in this section.

5.1.1 Some Limits are Incapable of Meaningful Enforcement in International Trade

As mentioned previously, many substances used in winemaking are grape-derived and are added only to adjust the levels of the identical substances, already naturally present in wine as it is produced. There is no chemical analysis that exists that can successfully determine the amount that has been added in contrast to the amount that was already in the juice from which the wine is being made. As an example, addition of grape-derived tartaric acid to grape must or wine cannot be distinguished chemically from tartaric acid that was already present in that grape must or wine. It follows that any numerical limit on the addition of such substances is not capable of meaningful enforcement in international trade. The only way to know how much of these sorts of treatment agents have been used is to consult production records. This can be done fairly readily by national jurisdictions, but in international trade, the authorities in destination markets seldom have the powers to inspect the production records in countries of origin. Furthermore, in times of depleted resources for enforcement activity, the addition of the correct amount of a substance (for which there is no public health concern) to wine will tend to take a very low priority. This makes such limits more symbolic than practical, and also tilts the trading environment in favor of unscrupulous producers who know that enforcement is essentially impossible and are prepared to exploit the minimal risk of detection. Honest producers, in contrast, make costly efforts to comply with such provisions, sometimes creating products and labels for several individual markets when their less law-abiding competitors may not go to such lengths.

5.1.2 Some Numerical Limits for Winemaking Practices are Open to Misinterpretation

Those limits concerning the amount of a substance that may be added in winemaking are sometimes misinterpreted. The result is an inadvertent barrier to trade. This is especially the case where the identical substance is already present in the wine and the addition is to adjust that pre-existing level. There has been at least one recent case where a numerical limit in regulations was mistaken by competent authorities as representing the total amount of that substance that may be present in wine, rather than the maximum amount that may be added to what was already present. The result was a technical barrier to trade which was probably inadvertent, and should have been entirely avoidable. Ideally, a system of regulations for winemaking practices at the international trade level would eliminate such possibilities.

6. Better Regulation

The need to resolve the regulatory issues that have been discussed in this paper is one that governments have wrestled with over recent years, both nationally and internationally. It has led to the development of concepts such as “Better Regulation” which can be distilled into the following precepts:

- Subsidiarity and Proportionality. Regulations should:
 - Add value for the public
 - Be designed for efficient and effective enforcement
 - Have the lowest financial impacts for business
- Simplification (regulations should be simplified as far as possible)
- Reduction in the administrative burden of regulations (for all stakeholders)
- Impacts should be favourable (economic, social, environmental)

Given the situation confronting global trade in wine, it is timely to seek an approach that conforms to principles of better regulation at this global level, while continuing to give freedom to governments to apply additional, non-trade inhibitory provisions they may deem important to the producers within their own jurisdictions in order to achieve objectives including quality guarantees.

7. A Possible Way Forward

There is an approach to the regulation of winemaking practices that addresses all of the issues discussed above, while maintaining necessary levels of protection for consumers. It also conforms to many of the principles of Better Regulation.

For those winemaking practices surrounding which there are no public health considerations, it involves the use of a concept known as Good Manufacturing Practices (or GMP) to govern the level of usage for a given treatment.

7.1 GMP Defined

Good Manufacturing Practices in general usage describes the methods, equipment, facilities, and controls for producing processed food. As the minimum sanitary and processing requirements for producing safe and wholesome food, they are an important part of the control systems that apply to the food supply. They are often implemented in practice by way of risk assessment-based procedures, requiring producers to understand their processes intimately and to focus controls in the areas where risk is greatest.

In the case of food additives (which most closely aligns with the use of winemaking treatment substances), the Codex Alimentarius Commission¹ considers “Good Manufacturing Practice” to mean that:

- the quantity of the additive added to food does not exceed the amount reasonably required to accomplish its intended physical nutritional or other technical effect in food;
- the quantity of the additive that becomes a component of food as a result of its use in the manufacturing, processing or packaging of a food and which is not intended to accomplish any physical, or other technological effect in the food itself, is reduced to the extent reasonably possible;
- the additive is of appropriate food grade quality and is prepared and handled in the same way as a food ingredient. Food grade quality is achieved by compliance with the specifications as a whole and not merely with individual criteria in terms of safety.

7.2 The Benefits of the GMP Approach

An approach to wine practice regulation at the international trade level can be envisaged in which the level of usage is permitted “according to GMP” for substances where there are no public health considerations. This approach also addresses the various challenges that were previously identified.

7.2.1 GMP and Product Safety

One assumption that is often made regarding GMP is that it sacrifices consumer health and safety in favor of producer flexibility. This is simply untrue, given the risk assessment basis of the GMP concept. Consumer health and safety is the primary concern of international scientific expert committees like JECFA as well as other advisory organizations such as EFSA. These organizations conduct safety assessments of food

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

additives and wine treatments that are consistent with current thinking on the subject and take account of recent developments in toxicology as well as other relevant sciences. Where they evaluate a substance and determine that there is no need to establish a numerical Acceptable Daily Intake value (ADI), they are stating that no known safety concerns exist. Thus usage of these substances according to GMP (at the minimum level needed to obtain the desired outcome) poses no risk to the consumer.

7.2.2 GMP and Flexibility

If usage according to GMP were to become an internationally accepted approach for the regulation of winemaking practices, producers would have much greater freedom to adapt as climate change progresses, as technical knowledge about wine continues to grow and as consumer preferences evolve. They would not have to wait months and even years for standards to be amended to enable them to respond to these developments. It should also be noted that if GMP was an accepted approach, regulatory bodies would not have to spend this additional time debating and implementing new regulatory limits. Furthermore, the adoption of such an approach for global trade in no way prevents nations and regions from developing stricter standards for their own producers in order to develop or maintain marketplace advantages relating to quality, culture or heritage, provided these do not inhibit free movement of goods in the international market.

7.2.3 GMP and the Eradication of Trade Barriers

The adoption of a GMP approach to winemaking practice regulation would result in the disappearance of many numerical limits that currently exist. There would, quite simply, be far fewer limits that could be inadvertently broken and thus far fewer cases of wine being denied market entry for reasons that have nothing to do with product or consumer safety. There would also be fewer numerical limits that could be misinterpreted and misapplied in trade.

Over the years, different approaches have been developed and implemented as means to reduce or eliminate trade barriers in regard to winemaking practices. These include harmonization of rules (as exists, for example, in the Common Market Organization (CMO) for wine in the EU), and also mutual acceptance of winemaking practices (as in the Mutual Acceptance Agreement for Oenological Practices developed in the World Wine Trade Group, where a wine made legally in one country will be accepted in the others, even if the winemaking practices are not approved there). These approaches each have their strengths and weaknesses. Adoption of a GMP approach, however, is a hybrid of the two in the case of agreed practices. It allows each producing country to use a treatment at the level needed in those circumstances, and this is then accepted elsewhere because there is no consumer deception or public health concern involved.

7.2.4 GMP and Enforcement

As discussed earlier, enforcement is impossible internationally for many winemaking treatments. However, the GMP approach renders enforcement of specific levels unnecessary. Enforcement resources can then be re-deployed to tackle other issues of higher priority, where there are concerns of public health and consumer deception.

8. Responses to Arguments Against the GMP Approach

Where the concept of the application of GMP as discussed in this paper has been considered previously, certain objections have been raised. For completeness, these are considered and answered in this section.

8.1 Usage According to GMP is no Limit at all

Where the concept of GMP is not well understood, some tend to consider that it represents a complete deregulation in which there is no restraint at all on producers. For the following reasons, however, this is a misconception of how GMP works in practice.

8.1.1 GMP is a *de facto* Limit, More Conservative than Most Numerical Limits

As we have seen, the principles of GMP only allow the use of treatment substances in the lowest amount possible (within reason) to achieve a desired technological or organoleptic result. This means that GMP is actually a *de facto* limit. Furthermore, in most cases, the application of this principle results in a *more* conservative outcome than the establishment of numerical limits.

For example, if a maximum use level of 4.0 g/L is established for a substance to accommodate variance in wine characteristics, but only 3.0 g/L is necessary to achieve the intended technical function in the wine under normal conditions, then GMP requires that *less* than the established numerical maximum use level for the additive be used.

8.1.2 Usage of Winemaking Treatment Agents is Limited by Cost

The use of substances at levels greater than that necessary to achieve the intended technical function is not economically feasible. This is because there is a cost associated with the use of every winemaking treatment

and, to remain competitive, a producer must minimize as much as possible the number and extent of such interventions.

8.1.3 Usage of Winemaking Treatment Agents is Limited by Product Quality Concerns

Winemakers need to be very careful when they contemplate the use of a winemaking practice. They know what they want to achieve in terms of the characteristics of the final product, but they are well aware that if they use a treatment to excess, they risk ruining the wine and making it unpalatable for consumers, which is an extremely costly error. As an example, no winemaker will deliberately add more tartaric acid to a wine than is required to achieve the desired consumer profile/taste. To do so would result in an unsaleable product. For this reason, winemakers will often conduct small scale trials on samples of a wine, to make sure that they are not over-treating it, before the treatment is scaled up to the production level.

8.2 GMP will Result in Consumer Deception

The argument surrounding consumer deception is built upon the idea that producers will utilize excessive wine making treatments to disguise poor quality grapes. In practice, any winemaker will readily confess that good wine cannot be made from bad grapes. The winemaker serves as caretaker of the quality inherent in each vineyard at the point when it is harvested.

Many winemaking practices are designed to rectify inadequacies in the raw materials of one sort or another so that the consumer can be presented with the best possible product given the variable nature of the grapes from which it is made. Even if good wine could be made from poor grapes (which it can't), the consumer is presented in the marketplace with a good wine that has no public safety issues associated, and can freely choose whether to purchase the same product on repeat occasions.

Another point to bear in mind here is that many of the numerical limits that are proposed in order to prevent deception of this kind cannot actually be enforced in the international trade situation, and will therefore prove totally ineffective in averting the problem if it actually were to arise. Additionally, as previously stated, the original introduction of limits for many winemaking treatments was based on production requirements in a particular winegrowing region, and not as a means of ensuring that consumers would not be deceived. To argue that the same limits now protect against consumer deception is a *non-sequitur*.

8.3 GMP will Result in Reduced Product Quality

The quality of wine will not suffer but will rather benefit from the ability to use winemaking treatments as needed. Restricting producers to inflexible, numerical winemaking treatment limits where no health or other valid consumer protection concerns are present can actually cause wine quality to suffer. Producers who aren't able to utilize winemaking treatments so as to bring out the very best quality naturally present are destined to create less palatable products, which will be less desirable and possibly unacceptable to consumers.

8.4 GMP limits by their very nature cannot be enforced

Some may object that a numerical limit can be objectively enforced. A GMP limit, because of its potential variability depending on circumstances, is much harder to control. However, it has been shown in this paper that for many winemaking treatments where numerical limits are applied, enforcement by analysis is impossible anyway, and this is the only kind of enforcement that is feasible in international trade where jurisdiction issues do not permit importing market authorities to inspect production records in the country of origin. In addition, as has been pointed out, use of winemaking treatments is self-limiting on grounds of cost and product quality, and a GMP limit is actually more conservative in most cases than a numerical limit.

9. GMP and Codex Alimentarius

It is worth noting that the general approach of the Codex Committee on Food Additives (CCFA) is to establish a numerical maximum use level for an additive if the Joint FAO/WHO Joint Expert Committee on Food Additives (JECFA) has assigned a numerical acceptable daily intake (ADI) for that additive. However, if JECFA has assigned a non-numerical ADI (e.g., "not specified"), assessment of exposure against the ADI is not necessary, and CCFA then typically assigns a maximum use level of GMP for the additive in question.

It follows that the approach advanced in relation to wine in this paper is already the recommended approach of the Codex Alimentarius Commission to its member governments in respect of all other processed foodstuffs.

10. Conclusion

In dealing with winemaking treatments and responding to the realities of the 21st century, global wine market, the use of GMP to regulate the addition of many substances in winemaking provides flexibility to producers to meet consumer demands and to respond to global challenges. At the same time, it relieves competent authorities of enforcement responsibilities that are effectively impossible to fulfil, and liberates resources for

activities where they can ensure an appropriate level of protection to consumers and provide a level playing field for producers around the world.

This paper has demonstrated that the default approach on food additives implemented by the Codex Alimentarius Commission should also work well in a global market for wine. This approach states that when JECFA has assigned a non-numerical ADI for the additive, assessment of exposure against the ADI is not necessary, and a maximum use level of GMP is most appropriate.