French Federation of Exporters of Wines & Spirits

Fédération des Exportateurs de Vins et Spiritueux de France

Comments

Concerning

U.S. Food and Drug Administration

Docket No. 02N-0276 – Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

and

Docket No. 02N-0278 – Prior Notice of Imported Food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

December 23, 2003

Comments of the

French Federation of Exporters of Wines & Spirits

Federation des Exportateurs de Vins et Spiritueux de France (FEVS)

in

Docket No. 02N-0276 – Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Docket No. 02N-0278 – Prior Notice of Imported Food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

December 23, 2003

1. The Interim Final Rules are likely to have negative effects on business confidentiality and trade secrets, as facility registration numbers are divulged then used without authorization. FDA should act to correct this situation. The issue of gray market sales is connected to the use of the registration number. The Interim Final Rules should be interpreted and applied so as to deter gray market sales.

FDA must be aware that the facility registration numbers issued under the Registration Rule have become a subject of controversy and a virtual traded commodity. The registration numbers frequently are demanded by buyers who want to place the numbers on invoices and by retailers, transporters and others. The Final Rule should end this situation.

Equally importantly, FDA should revise its rules regarding the use of registration numbers in general and on the Prior Notice in particular to protect legitimate buyers and distributors from unauthorized gray market imports. For example, the manufacturer's registration number could be required instead of being optional information. However, it would be necessary to allow for special circumstances, such as situations in which the shipper plans to export an old vintage wine from a manufacturer that has gone out of business so does not have a facility registration number.

2. The Interim Final Rules, in particular the requirement for a U.S. Agent, alter traditional commercial practices unnecessarily and add

costs to each transaction, with important negative consequences for small and medium sized businesses and for new entrants to the market.

FDA should reconsider aspects of the Interim Final Rules that alter traditional commercial practices. In particular, FDA should eliminate the requirement for a U.S. Agent. The U.S. Agent performs the limited role of information intermediary. A foreign company should not have to pay US$500 or more or to hire a new employee who will only notify the foreign principal – probably by telephone or email – in the unlikely event that FDA contacts the U.S. agent by telephone or email. Certainly a foreign-based agent could perform the same function promptly.

While the cost of a U.S. Agent might be inconsequential to a transnational corporation, which might even be able to assign the task to an employee at its U.S. subsidiary, the fee to employ a U.S. Agent is an important cost to small exporters and to new entrants to the market. Both small exporters and new entrants have less financial means and lower profits from which to pay the new fee. For them the US$500 (or more) expense is burdensome and appears both unreasonable and unnecessary.

3. The claimed compatibility of the Interim Final Rules as national security measures with the rules of the World Trade Organization is unconvincing and is more tenuous if the measures will be used to protect the safety of the U.S. food supply.

In the Comments on the Proposed Rules, FDA asserts that it believes that the Interim Final Rules are consistent with the international trade obligations of the United States. This assertion is not convincing.

The WTO security exception in Article XXI of the General Agreement on Tariffs and Trade 1947 is an exception that usually goes unchallenged. However, as with most WTO exceptions, the text requires that the action be "necessary", among other criteria. The complex and detailed Interim Final Rules – several hundred pages of requirements and interpretations of less than ten (10) pages of law – do not meet the WTO definition of necessary.

There are hints that the Interim Final Rules will be used as food safety measures. These rules were not preceded by a risk assessment, as required by the WTO Agreement on the Application of Sanitary and Phytosanitary Measures, and so are easily challengeable under that WTO Agreement.

Another approach is to judge the Interim Final Rules under the WTO rules that apply to technical barriers to trade. According to Article 2 of the WTO Agreement on Technical Barriers to Trade (TBT Agreement) a technical measure must not be applied with the effect of creating unnecessary obstacles to trade. The costs of compliance, the forced

changes to traditional commercial practices and the requirement of a U.S. Agent, among other requirements, are unnecessary obstacles to international trade. In addition a technical measure must not be more trade-restrictive than necessary. Again, each Interim Final Rule and the two Interim Final Rules in combination are highly trade-restrictive for the reasons stated above. Many current and potential exporters are likely to decide not to export rather than to comply, for example, because of the costs, the requirement to employ a U.S. Agent or the complicated new procedures. Less regulation in these areas would not add to the supposed risks of a terrorist attack.

Finally, the requirement to employ a U.S. Agent, which applies to foreign facilities but not to domestic facilities, seems contrary to the national treatment provisions of several WTO agreements, including the General Agreement on Trade in Services.

4. The scheme of names used in the Interim Final Rules must not infringe on geographical indications, such as Champagne and Cognac.

French, European Union and World Trade Organization (WTO) rules recognize intellectual property (IP) rights in geographical indications (GI's). Both Champagne and Cognac fall within the WTO definition of a GI. Even in the United States several of these names are protected under intellectual property law as certification marks, a form of trademark, and are recognized by the Department of the Treasury.

In exercising FDA's new role under the Bioterrorism Act, which gives it limited jurisdiction over wines and spirits, FDA must not infringe on GI's. In particular, it must understand that a GI cannot be a product name, a common or usual name or a brand. Since FDA has almost no experience with common or usual names for alcoholic beverages, the agency must be especially careful to conform to WTO commitments and to protect GI's, *e.g.*, when reviewing compliance with section 1.281(5)(ii) of the Prior Notice Rule.

A Geographical Indication, such as "Champagne" or "Cognac", indicates that the origin of the product is significant. GI's are defined in Article 22.1 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) as "indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin." A Geographical Indication must be protected, according to TRIPS Article 22.2 .

A Geographical Indication, such as Champagne, should not be viewed or required as the common or usual name on the Prior Notice form. A common or usual name, such as "red wine" or "white wine",

informs consumers about the nature of the product, not its geographical origin.

Another name mentioned in the Prior Notice form, the product code, also serves a purpose different from a GI. The product code identifies the industry, the production process and other information. A product code must not infringe on GI's. Thus the use of champagne and cognac in product codes raises concerns.

5. The "manufacturer" must be defined in both Interim Final Rules. FEVS suggests that the common definition should define the manufacturer as the last entity to conduct a processing operation, e.g., including bottling but excluding labeling.

The two Interim Final Rules do not have a common definition of manufacturer. The Registration Rule contains a definition of manufacturing/processing, in connection with determining which facilities must be registered. The definition focuses on operations rather than on an entity. The Prior Notice rule does not have a definition of manufacturer or manufacturing, but does require on the Prior Notice form the name and address of the manufacturer of a processed food. A definition of manufacturer is needed.

FEVS believes that the manufacturer should be the person who performs the last manufacturing/processing operation.

6. Conclusion

FEVS appreciates the opportunity to comment on the two Interim Final Rules. It urges the FDA to consider favorably the recommendations made in these comments and would be pleased to answer any question regarding the comments.

French wine production and marketing involve several participants and steps.

Initially there are those who grow the grapes, the cultivateur. They include individual grape growers (including legal persons), cooperatives of growers and some chateaux that grow their own grapes.

Label Terms:
AOC
VDQS
Vins de pays
Vins de table

These participants are located in a wine growing region. In France the place where the wine is grown, rather than the winemaker or grape variety, is of utmost importance. There are ten (10) regions, including Alsace and Lorraine, Bordeaux, Burgundy, Champagne, Languedoc-Roussillon, the Loire Valley and the Rhone Valley. Each region has its unique soil (texture, structure, acidity), landscape, regional and vineyard climate and vines, which are encompassed by the French word "terroir". is may be recognized through a Geographical Indication. Some links between the soil, climate and vines are recognized through the 350 governmentally recognized and controlled Appellations of Origin (AOC) for wines. A well-known AOC wine is Châteneuf-du-Pape. Another description that applies to a few products is denoted by the term vin délimitée de qualité supérieure (VDQS). Only wines that met certain standards regarding terroir and quality can be labeled AOC or VDQS . Vin de pays and vin de table describe wines with more basic qualities. The category determines what (if anything) may be stated on the wine label, concerning features such as vintage and grape variety. Other grapes are recognized by their community, such as Fronsac, Pomerol and Saint-Émilion in Bordeaux.

Within the region, a grower chooses to grow certain varieties of grapes. For example, in Bordeaux three grape varieties predominate: cabernet-sauvignon, cabernet-franc and merlot. In Burgundy, chardonnay is among the major grape varieties. Among the other

varieties are chenin blanc, pinot blanc, pinot noir, reisling and syrah.

The Growers sell their grapes to chateaux, cooperatives and to other winemakers (vigneron or cavist), who crush, mix, ferment and age the grapes into wine. In Champagne a different production process, called the méthode champenoise, is used.

The winemakers use the grape varieties and their own wine-making techniques to give a wine a particular character. Certain chateaux are known for the success of their techniques and produce "grand cru" and "cru bourgeois", such as Margaux, Pétrus and Haut-Brion in Bordeaux. Other well-known chateaux are Lafite-Rothschild and Pichon-Longueville. These wines may be further delimited, such as the Grave (from Haut-Brion) with the appellation Pessac-Léognan that carries the rank of grand cru classé.

Recognitions:
Region/GI
Varietal
AOC
Cru
Chateaux

It is usually at this stage that the business of preparing wines for sale (bottling and labeling) and marketing begin. In France these roles may be filled by the winemaker. However, often the winemaker turns one or more of these roles over to a broker called a "negociant", to a cooperative or to a merchant.

A negociant may act on its own behalf or for the winemaker. In the former case the negociant purchases the wine from the winemaker in bulk or in bottles, then stores and/or sells it. In the latter situation, the negociant may go onto the property of the chateau to bottle the wine, which subsequently can be labeled, stored and marketed by the chateau or by the negociant. Either the winemaker or the broker can store then market the wine within France and/or in foreign markets. Another actor – a freight forwarder – may then be called on to arrange for the export of the wine, although many small chateaux bottle, store, market and export their wines.

From Grower to Export Sale