# Grapes 101

## Understanding FSMA: Questions about new food safety regulations and how they relate to beverage alcohol producers

By Chris Gerling and Cortni Stahl

**Part 1. General Concepts**
The FDA Food Safety Modernization Act (FSMA) is the biggest change to food regulation since the original Food, Drug & Cosmetic Act was passed in 1938. In this article, we will answer common questions surrounding this newly signed regulation and how it relates to the grape and wine industry.

**What is FSMA?** Signed into law in early 2011, this regulation "aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it," according to the FDA.

**Is wine covered under FSMA?** Yes, alcoholic beverages are specifically mentioned (more later) in the regulations. Wineries are food manufacturing plants in the eyes of the FDA, and must also meet the requirements for these types of facilities.

**How can manufacturing plants focus on prevention?** First they must prepare for lots of acronyms and initials. There are three major programs on which the FSMA framework relies: good manufacturing practices (GMPs), standard operating procedures (SOPs) and, most importantly, hazard analysis and critical control points (HACCP). To sum each of them up as briefly as possible:

- **GMPs**- creating a work environment that makes safe food production possible.
- **SOPs**- documenting procedures so every (trained) employee can carry out every work activity effectively every time.
- **HACCP**- identifying the most important steps in the production process and determining ways to ensure that these actions have been performed correctly. FSMA now uses terms like "risk-based preventive controls" to refer to HACCP-like procedures.

**How are alcoholic beverages covered in the regulations?** FSMA has seven sub-parts, and alcohol producers licensed by the Alcohol and Tobacco Tax and Trade Bureau (TTB) are exempt from subparts C (hazard analysis and risk-based preventive controls) and G (supply chain program). Parts D (modified requirements) and E (withdrawal of a qualified facility) are basically procedural, leaving parts A

(general provisions, including education and training), B (current good manufacturing practices) and F (requirements applying to records that must be established and maintained) to be dealt with. See *Table 1* for a synopsis of the above.

*Table 1. FSMA Preventive Controls for Human Food- sub-parts and applicability for TTB-licensed alcohol producers. Green - Applicable and requiring action. Yellow - Applicable, but mostly procedural. Red - Alcohol producers are exempt.*

| Subpart | Title |
|---|---|
| A | General Provisions, Including Education and Training |
| B | Current Good Manufacturing Practice |
| C | Hazard Analysis and Risk-Based Preventive Controls |
| D | Modified Requirements |
| E | Withdrawal of a Qualified Facility |
| F | Requirements Applying to Records that must be Established and Maintained |
| G | Supply Chain Program |

**What is a hazard, and why are alcohol producers exempt from the hazard analysis?** FDA defines a hazard as any agent that has the potential to cause illness or injury to a consumer. There are three hazard categories: biological (foodborne pathogens), chemical (like contamination from a cleaning chemical) and physical (such as a piece of broken glass from a bottle). Biological hazards are most frequently encountered and therefore the highest priority in HACCP-like systems. Alcohol is toxic to pathogenic spoilage organisms, so alcohol is considered "low-risk," thereby exempting manufacturers from subparts C and G.

**Isn't alcohol still at risk from chemical and physical hazards?** Yes, it is. While beverage alcohol producers aren't strictly required to create a hazard analysis, they are still liable for any injury caused and as such should develop plans to address these risks. Consider the most likely sources of chemical (e.g., detergents and sanitizers, fining agents, $SO_2$, other preservatives) and physical (broken glass) hazards, and steps that can be taken to prevent them. Examples include measuring cleaning agent concentration before use, measuring $SO_2$ after any addition, and ensuring all bottles are turned upside down and blown out with inert gas before filling.

**What about workplace dangers that can injure employees? Are those hazards?** Strictly speaking, no. Dangerous conditions in the workplace are the purview of the Occupational Safety and Health Administration (OSHA). FSMA regulations are focused on consumer safety.

**How can I make sure my operation is complying with subparts A, B and F?** The short answer is training and records. Employees who work in production can access Cornell's new online cGMP training through the Institute for Food Safety.

Tasting room staff could take ServSafe training. Make sure that standard operating procedures are well-documented, especially anything relating to sanitation or additions to the product. Keep records of anything that is brought into or sent out of the facility, including lot numbers and origin or destination. Finally, make sure everything in the facility is labeled.

**If the law has been in place since 2011, why is there so much attention on FSMA now?** While the law has been in effect for six years, some of the training and inspection deadlines were set for 2017 and 2018.

**Will I be inspected? How will it work?** The FDA is hoping to inspect all registered facilities by 2018. These inspections don't have to be announced in advance, although the possibility of a surprise inspection by a federal agency is not a new thing for beverage alcohol producers. Inspections may be handled by state agencies in some cases, especially for smaller facilities. FDA is interested in "systems-based" inspections, which means seeing the plan more than the execution. They want to see records and SOPs as opposed to how well an employee cleans a tank.

See **Part 2** (PDF link below) for a flowchart for beverage alcohol producers to navigate the specifics of FSMA regulations.

## Part 2: A flowchart containing specific language from the regulations and links to FDA resources

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