

# The New Language of Food Gases

By Bob Yeoman



The US Food and Drug Administration (FDA) is in the home stretch of finalizing a new and sweeping set of changes to food safety regulations ushered in by the Food Safety and Modernization Act (FSMA), which was signed into law in 2010. During the last six months of 2013, the FDA was busy publishing their view of the food safety world to come in the form of new regulatory proposals for public review and comment. During that same period, the agency was holding public hearings to interact with the public and collect further comments on many of their proposals. In the often lengthy US regulatory process, public hearings are usually one step — and sometimes the last steps — before final regulations are issued.

See “Changes Coming to the Food Supply Chain,” CryoGas, May 2013, p. 40.

**This article examines some of the new language that welding and gases distributors will need to learn in order to adapt their business practices to new FDA regulations.**

The FDA has felt public pressure for food safety regulations building on two fronts. The US continues to experience major recalls of contaminated food products that are diligently reported in the media and keep the public focused on food safety. Food safety advocates also continue to press court actions that seek to have the FDA move faster on food safety regulations. Key members of Congress are exerting their own influence on agency executives to get these new regulations implemented as quickly as possible. It is our expectation that by 2014 and early 2015 the FDA will finalize the

bulk of these new food safety regulations, which will initiate the countdown to mandatory implementation.

As these new regulations start to phase in they bring with them a new regulatory language rife with terms that will be unfamiliar to many in the gases industry. This article examines some of the new language that welding and gases distributors will need to learn in order to adapt their business practices to new FDA regulations. While the focus here is primarily on carbon dioxide and nitrogen, the same basic issues we discuss apply to all Food or Beverage Grade gases.

## Food Grade vs. Beverage Grade Analytical Specification Comparison

Contaminant	ISBT - CGA I		Rationale	Food Chemical Codex - CGA H	
	Method	Spec		Method	Spec
Assay	Wet Chemistry or GC	≥ 99.9%		Wet Chemistry	≥ 99.5%
Odor of Solid CO <sub>2</sub>	Olfactory	None	Taste	Olfactory	None
Odor & Taste in H <sub>2</sub> O	Olfactory	None	Taste	Olfactory	None
Identification	Detector Tube	Positive		Detector Tube	Positive
Oxygen	Paramagnetic	< 30 ppm		Paramagnetic	< 50 ppm
Carbon Monoxide	Detector Tube	≤ 10 ppm		Detector Tube	≤ 10 ppm
Ammonia	Detector Tube	2.5 ppm max			
Nitric Oxide	Detector Tube	≤ 2.5 ppm		Detector Tube	≤ 5 ppm
Nitrogen Dioxide	Detector Tube	≤ 2.5 ppm			
Non-Volatile Residue	Residue Weight Test	10 ppm max		Residue Weight Test	10 ppm max
NV Organic Residue	Residue Weight Test	5 ppm max		Residue Weight Test	10 ppm max
Phosphine	Detector Tube	≤ 0.3 ppm			
Hydrocarbons as C <sub>2</sub> H <sub>2</sub>	Gas Chromatography	≤ 50 ppm max		Gas Chromatography	≤ 50 ppm
Acetaldehyde	Detector Tube	≤ 0.2 ppm		Detector Tube	≤ 0.5 ppm
Aromatic Hydrocarbon	FID Analyzer or GC	20 ppb max			
Total Sulfur Content	Sulfur Analyzer	≤ 0.1 ppm		Sulfur Analyzer	≤ 0.5 ppm
Sulfur Dioxide	Detector Tube	1 ppm max			
Moisture	Detector Tube	≤ 20 ppm		Detector Tube	≤ 20 ppm
Hydrogen Sulfide	Detector Tube	≤ 0.1 ppm		Detector Tube	≤ 0.5 ppm
Carbonyl Sulfide	Detector Tube	≤ 0.1 ppm		Detector Tube	≤ 0.5 ppm
HCN	Infrared Analyzer	None			
Oil / Grease	Infrared Analyzer	5 ppm			
Methanol	Infrared Analyzer	10 ppm			

Figure 1

Source: B&R Compliance Associates LLC

## Redefining Food

Many welding and gases distributors currently don't even recognize they are in the food business. While being in the food business may have been debatable in the past, the coming FDA changes clarify the definition of Food and will put many distributors squarely in the food business. Under FSMA the FDA now defines food as "... a raw, cooked, or processed edible substance, ice, beverage, or ingredient used or intended for use or for sale in whole or part for human consumption or chewing gum." This means that any gases used as ingredients in food or beverages are themselves considered food. So, clearly carbon dioxide and nitrogen used to manufacture beverages are now Food under Federal Law! It is also pretty obvious that gases sold as Food Grade are clearly intended for use and for sale for human consumption, and that now makes them Food under the law.

The FSMA's definition of a Food Processing Facility broadens the scope of the facilities which will be regulated under this new law. Traditionally plants that did not fill cylinders of Food Grade gases, but simply stored and sold food gas cylinders filled by someone else, were considered exempt from the law. Under FSMA, the FDA defines a Food Processing Plant as "... a commercial operation that manufacturers, packages, labels, or stores food for human consumption, and provides food for sale or distribution to other business entities..." So, unlike medical gases where you must fill cylinders to be regulated by the FDA, when it comes to food the law now says that any facility that simply stores Food Grade cylinders of gas is regulated under FSMA. In the simplest of terms this means that welding and gases distributors that fill, sell, or exchange even an occasional CO<sub>2</sub> cylinder for home beer carbonator units are selling Food, and under FDA regulations are a food processing plant, even if someone else filled the cylinders for them.

## Beverage Grade vs. Food Grade

The next piece of new language involves the various grades of gas currently being sold to food and beverage customers. Throughout the industry we see the term "Food Grade" and "Beverage Grade" used interchangeably by many companies, both gas suppliers and customers alike. However, Food Grade and Beverage Grade gases are significantly different animals.

## A PRODUCER AND SUPPLIER PERSPECTIVE

New FDA regulations for food are extensive and complex and will require gas producers to invest more time and energy in their food and beverage gas manufacture and distribution processes.

*CryoGas International* spoke with Terry Scanlan, Strategic Customer Manager, Linde Gases and Sal Calandra, Head of Quality & Food Safety for Linde NA, about the new FDA regulations and their impact on their food and beverage business. Calandra is also the Chair of the Beverage Gas Committee for the International Society of Beverage Technologists (ISBT) and the Food Gas Committee for the Compressed Gas Association (CGA). Linde is the world's leading supplier of beverage and food gases and related applications.

**CryoGas:** Are your customers asking about the difference between food and beverage grade gases?

**Terry Scanlan:** Yes — both the global food and beverage industries seek continuous improvement and protections along the entire supply chain, from farm to fork. Today, both individual companies and industry associations are driving the integrity of the food chain to ensure that the highest standards are applied universally. The food and beverage companies that operate on the retail front line with consumers are now holding their suppliers to even higher standards than before in order to mitigate food safety risks in the food chain. Industry Associations such as the Global Food Safety Initiative (GFSI), CGA, and ISBT are examples where industry participants work together to develop common standards, processes, and protocols.

**CryoGas:** How does this manifest itself in the supply chain?

**Terry Scanlan:** We aim to focus more on understanding the specific customer's requirements and then to mutually agree to the standards required to meet the quality and safety requirements for that particular product. Linde recently made the commitment that all its Linde Food Grade carbon dioxide production plants would align with the GFSI by gaining FSSC22000 certification. There also is an education process with some customers. We educate customers and distributors about new regulations, such as FSMA, and also about the purity differences between Food Grade and Beverage Grade product as defined by industry associations such as CGA and ISBT.

**CryoGas:** Have the new regulations caused changes in Linde's supply chain for CO<sub>2</sub> and nitrogen, especially in your production and distribution processes?

**Sal Calandra:** The new regulations have caused minimal changes in our production or distribution processes. This is partly because our key customers already require that we provide the intent of FSMA in advance of the regulations and in some cases obtain certification to a GFSI benchmarked scheme, FSSC 22000. However, the real reason that the regulations had little impact is that safety, including food safety, is a basic prerequisite for us and any business activity we undertake.

**CryoGas:** In 2010 Linde North America received FSSC 22000 certification for its nineteen beverage-grade carbon dioxide facilities. Does that certification impact Linde's ability to meet new FDA rules and regulations for food? If so, how?

**Sal Calandra:** Absolutely. The efforts to certify our CO<sub>2</sub> plants enhanced our understanding of the new food safety regulations and how they apply throughout our business. It has also caused us to proactively implement a FSMA compliant food safety management system for very low food safety risk products such as oxygen, nitrogen, and argon.

**CryoGas:** How are you educating your sales team about new regulations?

**Terry Scanlan:** Linde's training is built around bringing awareness to the sales teams, both directly and through our distributor network. We are providing training to the various sales teams so that they are aware of the new industry regulations and how we might support our customer's programs. It is important for the Linde sales team to understand that Linde has internal teams in Quality and Supply that are available to assist the Linde customer. Supplying products and services is not enough today; an education component also is important as the Linde customer seeks to understand how our programs fit into their processes in a complete, secure, and food safe supply chain.

**CryoGas:** Thank you Terry and Sal for sharing your knowledge of food safety regulations and their impact on the food and beverage business with our readers.

The Compressed Gas Association (CGA) (*cganet.com*) is responsible for some of the confusion around Food and Beverage Grades in our industry with their standards. For example, CGA Grade H for carbon dioxide is called “Food Grade,” and conforms to the Food Chemical Codex (FCC) analytical specifications for that product. CGA Grade I for carbon dioxide is called “Beverage Grade” and conforms to the International Society of Beverage Technologists (ISBT) analytical guidelines. The confusing part comes from the same CGA publication which also states that Grade H is acceptable to carbonate beverages, which effectively creates two Beverage Grades.

While the gas industry appears to be confused about which grade of CO<sub>2</sub> to use for beverages, the major beverage firms have made it quite clear they now only accept Grade I for use in carbonating their products. It is time for CGA to eliminate this dual

standard and update their carbon dioxide specification to reflect today’s market place reality, which is that CGA Grade I/ISBT Guideline is the appropriate and only acceptable specification for Beverage Grade carbon dioxide. The same issue will have to be dealt with for the Beverage Grade nitrogen specification once it is finally released by ISBT.

There are significant differences in the carbon dioxide product quality specifications between Food and Beverage Grades. For example, the analytical specification for Food Grade CO<sub>2</sub> has a minimum purity of 99.5 percent, and includes testing mainly for common/traditional CO<sub>2</sub> contaminants. On the other hand, the analytical specification for Beverage Grade stipulates a minimum purity of 99.9 percent and includes a broader range of contaminant tests. Even more important, for most of the contaminants the two grades share in common the specifica-

tion is much more stringent for Beverage Grade. While some of these differences are small they have been shown to be highly important. This is because Beverage Grade’s tighter analytical specifications are an evolution of customer requirements derived from actual testing on the effect of carbon dioxide contaminants on product quality performed by the beverage industry. The results of these tests concluded that the contaminant levels acceptable in Food Grade product can cause significant problems, such as inducing undesired tastes or odors, when used to carbonate high quality beverages.

### Product Pedigrees

Like medical gases the pedigree for Food and Beverage Grade products starts at the bulk supplier. Firms selling Food Grade gases, under Federal law, must have, at a minimum, a documented “Food Grade” pedigree back to the bulk supplier. Like-

**HARPC Seven Elements**

- 1. Risk Assessment**  
 Determine Hazards of each process at each facility.
- 2. Risk Based Preventative Controls**  
 Policies and procedures that define how risks are eliminated or reduced to acceptable levels.
- 3. Effectiveness Monitoring**  
 Interlocking system of process monitoring and employee/management communications.
- 4. Corrective Actions**  
 Ability to identify weak spots and new hazards, develop corrective actions, and ensure adequate remedial plans are implemented.
- 5. Compliance Verification (Facility Audit)**  
 Each facility shall be audited to determine if preventative controls are adequate and effective.
- 6. Recordkeeping and Documentation**  
 Documentation of key process steps together with the proof that the preventative controls are effective.
- 7. Reanalyze**  
 Program shall be assessed on an on-going basis by management, as well as when changes are made or new hazards are introduced.

Figure 2

Source: B&R Compliance Associates LLC

wise, firms selling “Beverage Grade” must be able to document a Beverage Grade pedigree back to the bulk source. While not as widespread a practice as a few years ago, there are still firms that purchase industrial grade carbon dioxide, but sell Food and Beverage grades of that product once it is put into cylinders. FSMA will allow firms to downgrade carbon dioxide with a Beverage Grade pedigree and sell it as industrial grade, but the reverse will be illegal. In other words, to sell Food Grade carbon dioxide in cylinders you have to start with bulk product that was manufactured and delivered to you as Food Grade. The same holds true for Beverage Grade.

Understanding these various requirements is all part of developing a common language around Food Grade vs. Beverage Grade. Welding and gases distributors need to understand that when providing one of these two grades of gases it is not just the purity specification that defines the grade. The definition of the grade also involves the contaminant testing and the ability to trace the product’s pedigree back to the source. Selling Beverage Grade gases means there is a larger set of product expectations involved than just providing a Certificate of Analysis with the words “Beverage Grade” on it.

### The Rise of Risk Assessments

Another new acronym being introduced by the Food Safety and Modernization Act is Hazard Analysis and Risk Based Preventative Controls, or HARPC. This concept of assessing risk and basing your controls on managing those risks to Food Safety is the centerpiece of the FDA’s new regulatory approach to regulating food. HARPC is a seven step process, which is outlined in the Figure 2. (I will be covering HARPC in more detail in a future article in *CryoGas International*.)

The whole HARPC process begins, ends, and is guided at each of the seven steps by a focus on hazard and risk identification and management. The tool for assessing risk favored by the FDA is HACCP, which stands for Hazard Analysis of Critical Control Points. We predict HACCP is yet another acronym that distributors in the food business should expect to become intimately familiar with over the course of the next few years.

See “Changes Coming to the Food Supply Chain,” *CryoGas*, May 2013, p. 40.

## A DISTRIBUTOR’S PERSPECTIVE

FDA is in the final stages of delivering new food regulations, which will usher in a new language that distributors of Food and Beverage Grade gases will have to learn. While gases distributors would prefer to have these new requirements and associated language delivered as part of one clear document, law, or regulation, this is not the case. FDA is following the Federal Rulemaking Process of Notice and Comment they use to introduce all new regulatory requirements. This is a top down driven process with information being delivered to the public via the published rules, FDA guidance documents, and public hearings to collect comments. Distributors who do not regularly read the *Federal Register* may only find out about new regulations when FDA comes to visit sometime in the future.

These new regulations are extensive and complex, and will require firms to invest more time and energy into the Food and Beverage gas manufacture and distribution processes. It will also require learning or tapping into additional expertise to build and manage a compliant food and beverage distribution operation.

*CryoGas International* spoke with Craig Wood, President of O.E. Meyer, a successful Midwest distributor of industrial, medical, a specialty gases — including food and beverage gases — about the new FDA regulations and their impact on his business.

**CryoGas:** When we profiled O.E. Meyer in our magazine (“O.E. Meyer: A Company on the March in Midwest Markets,” *CryoGas*, August 2012, p. 47), you reported that you saw a lot of opportunity to grow your share of the beverage market with liquid CO<sub>2</sub> microbulk delivery. Has this worked out well and have the new FDA regulations slowed the process.

**Craig Wood:** Our microbulk CO<sub>2</sub> business is gaining traction, yes. We already had well-defined Standard Operating Procedures (SOP) in place for FDA compliance in regard to our medical gases business and now we have the same for beverage CO<sub>2</sub>. So operationally, from a regulatory compliance perspective, we are well-positioned to meet the new FDA requirements for beverage CO<sub>2</sub> for our customers and to grow our CO<sub>2</sub> beverage business. Regulations will not slow us down.

**CryoGas:** How is FDA compliance regarding food and beverage managed at your company?

**Craig Wood:** We have a dedicated internal compliance officer for beverage gases and an associated team of people in charge of meeting all regulations, including those of the FDA. As I mentioned, O.E. Meyer already had in place a compliance program, managed by B&R Compliance, for our medical gases business. Together with Bob Yeoman and his team, we used this as the template to develop a similar SOP for beverage CO<sub>2</sub>. This will enable us to meet all new regulations going forward. Along with working with B&R Compliance, the benefits of being a Linde Platinum Distributor has significantly expedited the process of developing a well-rounded program. O.E. Meyer is fortunate to have the experience and resources to develop a really strong beverage compliance strategy.

**CryoGas:** Thank you Craig. We appreciate the insight you bring to this discussion.

Once FSMA takes full effect, every food facility in America will be required under Federal Law to conduct and document a HACCP risk assessment. When conducting that assessment firms must consider physical, chemical, biological, and radiological sources of food safety contamination (risks). The risk assessment must also assess points in the manufacturing process where food safety risks can be introduced or become concentrated. Finally a risk assessment will determine the process points where Food Safety hazards can be eliminated or controlled to an acceptable level. In just the last few months the FDA has added to the list of food safety risks that must be considered. In

February 2014, the FDA introduced a new Food Defense rule requiring firms to address intentional sources of contamination in their risk assessment. This means firms must consider the potential for a third party seeking to intentionally introduce a food safety hazard or contaminant into their product and how the firm can best detect and defend against that issue.

### Food Safety Plans

Using the output of risk assessment, firms will be required to create a food safety plan. The term food safety plan is somewhat of an acronym itself. Food safety plans will outline the relevant hazards and risks and spell out

the framework for addressing them. The plan will outline the firm's detailed approach to assessing and controlling identified risks and hazards. The plan also will incorporate the mandated food safety prerequisite programs for compliance with the various FSMA requirements, such as product traceability, recall, employee training, process documentation, etc. For many distributors already in the gas business, elements of their food safety plan might resemble sections of their medical gas manual, such as product lot numbering. Other elements, such as the risk assessment output and the actual food safety plan will be items new and unique to those firms.

Medical gas manufacturers and firms with an ISO certification will already be familiar with managing and approving procedures for their business. Under FSMA, the FDA takes this process to a whole new level. Every food safety plan must be reviewed and approved by a Qualified Individual (QI), which is yet another new acronym in the Food Safety lexicon. QI cannot be just anyone designated by

the company to conduct these reviews. The FDA is establishing regulations setting out minimum educational and experience requirements that a QI must possess in order to conduct these reviews and grant plan approval. QI criteria is expected to be a blend of training and experience in HACCP execution, knowledge of Food Safety Regulations, and experience in food safety auditing combined with a background in the food industry. The FDA has made it very clear in the FSMA language they do not expect smaller firms to have the capability to create their own QI. They also anticipate some firms may not be willing to invest the necessary time, effort, and money to train a QI to meet their criteria. As a result, the FDA built into FSMA the ability for smaller firms to use a third party as their Qualified Individual to do reviews and approvals for them. In fact, this is very likely the FDA's preferred approach for small- to medium-sized firms. In all likelihood most firms will end up forming a long-term relationship with their QI, as, in addition to the initial plan approval, any

changes to the HARPC plan must be approved by the QI and plans need to be reviewed and reapproved every three years at a minimum.

### Be Prepared

The new language of food and its associated acronym's will soon be part of the day-to-day dialogue in the gases industry. Teaching the industry and our customers the difference between Food Grade and Beverage Grade — and how to recognize that difference — is vital to preserving our industry's well-deserved reputation for safety in the public interest. Our industry needs to make sure going forward that the term "Safety" also includes "Food Safety" when referring to Food and Beverage Grade gases. B&R is already well ahead of the curve in FSMA compliance and is prepared to assist your company learn this new food safety language. For questions on food safety, medical or industrial gases, or bulk systems at healthcare facilities give us a call or drop us a line. ■

**Bob Yeoman** is President and CEO of B&R Compliance Associates LLC (Lehigh Valley, PA), a consulting firm specializing in medical gases, safety management, and other regulatory compliance management issues relating to the compressed gas industry. He can be reached at (610) 868-7183; Email bob.yeoman@brcompliance.com.



**IG,China 2014**

第十六届中国国际气体技术、  
设备与应用展览会  
16TH IG, CHINA 2014



**NGVEXPO  
CHINA 2014**

第六届中国国际天然气汽车、发动机、加气站  
技术、设备与应用展览会  
NGV EXPO, CHINA 2014

[www.igchina-expo.com](http://www.igchina-expo.com)  
[www.ngvexpo.com](http://www.ngvexpo.com)

**2014.9.24-26 北京全国农业展览馆**  
**Beijing National Agriculture Exhibition Center, China**

☎ 13910831620  
18610806092

✉ [ig.china@ait-events.com](mailto:ig.china@ait-events.com)  
[ngv@ait-events.com](mailto:ngv@ait-events.com)




官方微信公众平台：中国气体  
微信号：IG\_CHINA

扫描二维码即可登录  
展会官网预登记参观

**主办单位**  
Organized by  
中国工业气体工业协会  
China Gas Industry Association



**协办单位**  
Co-organized by  
国家燃气汽车工程技术研究中心  
China National NGV Engineering Research Center  
中国工业气体工业协会液化天然气分会  
China LNG Association




**承办单位**  
Produced by  
北京亚艾特展览有限公司  
AIT Events Co., Ltd.

