The Regulatory Landscape of Natural Flavors

What it means for the F&F industry when "natural" goes mainstream

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Natural and clean-label flavors and fragrances are in high demand. According to a recently published Datamonitor report, consumers today increasingly want to do the "right thing," and follow the latest trends in the natural products market.[a] Meanwhile, ongoing market research shows that consumers are demanding natural flavorings. "Natural" has become part of the consumer's mainstream vocabulary.

In recent years, consumer confidence in the food supply has decreased as a result of well-publicized product recalls and other food scares, as well as a general distrust of food science. As a result, many consumers now question where their food comes from, how it is produced and what is in it. They are interested in authentic, natural flavors; they want to understand what they're eating. Above all, they demand transparency.

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This trend is recognizable in the marketplace; "natural," "fresh," "wholesome" and "balanced" are buzzwords seen in marketing and food packaging. But what is labeled "natural" on food packaging may not be the same as the consumers' actual understanding of the term. Natural does not necessarily mean that an ingredient comes from nature. With a great number of new technologies available to the food and beverage industry, ingredients are produced in a wide variety of ways. So, what qualifies an ingredient to be labeled as natural and what is implied by the term?

Regulatory Complexity

What seems to be an easy question to answer may turn out to be rather complex. Adding to the complexity is the fact that the definition of a natural ingredient differs from country to country. Authorities of the European Food Safety Authority (EFSA; *www.efsa.europa.eu/*) require a different set of qualifiers than their counterparts at the US Food and Drug Administration (FDA; *www.fda.gov*). In the existing regulatory system, the FDA regulates natural flavors based on the Food Additives and Amendment Act (FAA) of 1958 as either generally recognized as safe (GRAS) or approved for use. In addition to these supranational and federal authorities, there are many other government and industry bodies involved in the creation of rules and regulations governing food safety and quality.

In the United States, the Flavor and Extract Manufacturers Association (FEMA; *www.femaflavor.org*) is also involved in ensuring food safety. FEMA maintains a list of more than 2,500 ingredients and substances that are GRAS. FEMA's list was established as part of a GRAS assessment program established after federal authorities recognized that the lengthy food application process, which is part of FAA, was unnecessary for a large number of substances with a long history of widespread and apparently safe use.[b] The US Department of Agriculture (USDA) also maintains a specific definition for "natural flavoring," limiting its regulatory authority to meat and poultry only. Furthermore, the National Organic Standards Board (NOSB), a federal advisory committee, advises the federal government on issues related to "natural" and "organic" substances as defined by the Food, Agriculture Conservation, and Trade Act (FACT-Act) of 1990.

In Europe, EFSA is the foundation of European Union (EU) risk assessment concerning food safety. As an independent scientific committee, EFSA works in close collaboration with national authorities and in open consultation with the industry, and is directly involved in the evaluation of flavors and fragrances as additives and ingredients. The Food Chemical

[a] 10 Trends to Watch in Natural Products in 2012; published by Datamonitor on June 13, 2012; *www.datamonitor.com*

[b] Overview of Flavor Additives, prepared for the USDA National Organic Program and the National Organic Standards Board, October 14, 2005; *www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5088008*; last accessed: August 24, 2012

Codex (FCC), a compendium of internationally recognized standards for determining the purity and quality of food ingredients, and the Joint FAO/WHO Expert Committee on Food Additives (JECFA)—the joint committee of the Food and Agriculture Organization of the United Nations and the World Health Organization—also provide specifications that must be met for food ingredients to be listed as natural. The further involvement of a great number of national regulatory bodies, each with different levels of country-specific classifications, may lead to confusion for both suppliers and buyers.

To make matters worse, the industry accepts a wide variety of categories in which ingredients can be classified as "appropriate" for food applications. These categories make the standardization of the regulatory landscape more complicated because what is deemed natural may fall within multiple classifications (e.g., GRAS, halal, kosher, organic, natural, etc.).

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Recently, the European Regulations on Flavorings (Regulation EC No 1334/2008) simplified some of these classifications. (Some flavorists may disagree.) The European directive no longer makes a distinction between "natural identical" and "artificial." Furthermore, the definition of "natural flavoring substance" now also includes a reference to the process that is allowed in the production of the flavoring compound.

However, with all the regulatory and industry demands on food safety and security, a universal standard for food ingredients, including natural flavors and fragrances, is sorely missed. Hence, navigating this increasingly complex landscape of regulatory requirements, consumer demands and industry standards may be a growing challenge for the food and beverage industry, including suppliers and buyers.

What is Natural?

There is currently no universal definition of natural or natural ingredients that can be simultaneously used by consumers and the food and beverage industry. In general, the term natural in the food and beverage industry is both a technical and legal term that does not necessarily mean the same as the commonly understood consumer idiom, i.e., minimally processed.

The US and European authorities are generally leading other global bodies when determining whether a flavor is natural or artificial. While these regulations are very similar, and are often haphazardly combined by suppliers and consumers to form their own definitions of natural, there are distinct differences between the two directives.

The definition of natural flavor under the US Code of Federal Regulations (21 CFR 101.22a)[c] refers to "… an essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis." Products are considered natural flavors when they are derived from products such as a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, extracts, oleoresin, meat, seafood, poultry, eggs, dairy or a group of materials recognized by the US FDA as "natural starting materials" whose significant function in food is as flavoring rather than adding nutritional value. According to federal regulations, a variety of processes can be applied to get natural flavors or ingredients. The US definition focuses on how the flavor is derived from a natural source, rather than the process being applied.

The FDA definition of natural flavors also refers to other sections of the US Code of Federal Regulations. Section 172.510, for example, lists natural flavoring substances and natural adjuvants, including immune boosting substances, such as aloe, rhubarb root and sarsaparilla.

The European definition, while similar, stipulates that the "source material must be vegetable, animal or microbiological" and "must be produced by a traditional food preparation process." An important difference between the US and European regulations is that the European directive limits the processes acceptable for producing natural flavors. Furthermore, the European directives require that a natural substance has to be identical to that found in nature and cannot be altered.

The distinction between natural flavors and artificial flavors is often very limited and based on the source or the process in which identical chemicals are produced. In the United States, products need to be marketed as artificial or synthetic if the process is not approved, while in Europe this material may still be called natural.

The regulatory complexity for what is considered natural also carries over into food labeling requirements. In most instances, the US regulations for food labels either describe flavors as natural or as natural flavor. On the other hand, the European definition is generally broader, including the designation "natural flavoring substance." However, to qualify for this designation, the European directive (EU 88/388) requires a numerical minimum percentage of the flavoring compound (e.g., natural "x" flavoring).

Example: The Origin of "Natural" and "Artificial" Vanilla Flavoring

Vanillin, the molecule responsible for the characteristic flavor of vanilla, was first isolated from vanilla pods by Theodore Gobley in 1858.[1] By 1874 vanillin, or 4-hydroxy-3-methoxybenzaldehyde, was manufactured from glycosides of pine tree sap. Today, vanillin can be produced in a number of different ways. According to both US and European directives, the method used in producing vanillin determines whether the flavoring product can be labeled as "natural" or "artificial."

Both US and European regulations allow the claim natural when vanillin is directly extracted from vanilla pods. When vanilla extract is derived from fractional distillation, a process by which components in a chemical mixture are separated according to their different boiling points to isolate vanillin, the labeling on the consumer product may include natural vanilla flavor in both the US and Europe. The same claim can be made if vanillin is made through different fermentation processes. Vanillin made from a variety of natural sources, including coffee beans, apple, wheat bran and orange pips, through a fermentation process using a starting material, or precursor, such as ferulic acid (a hydroxycinnamic acid) is also called natural according to both the US and European regulations. However,

[c] Electronic Code of Federal Regulations; GPO Access; *http://ecfr.gpoaccess.gov/cgi/t/text/textidx?c=ecfr&rgn=div8&view=text&node=21:2.0.1.1.2.2.1.1&idno=21*; last accessed: August 24, 2012

this claim differs when fermentation includes other products, such as guaiacol, a colorless aromatic oil usually derived from guaiacum or wood creosote.

Vanillin produced from lignin, a natural polymer found in wood that is broken down using an alkali and oxidation agent to create a synthetic or artificial version of vanillin, cannot be referenced as natural. Both US and European directives require this material to be labeled as "artificial vanilla flavor."

Finally, ethyl vanillin, or 3-ethoxy-4-hydroxybenzaldehyde, a molecule not found in nature and not chemically identical to vanillin, may be labeled "artificial vanilla flavor" in the US, while in Europe this product would be labeled "vanilla flavoring." The absence of natural on the label is a clear indication that the product is artificial, or synthetic.

Standardization

While technical and chemical aspects of the production and extraction of flavors has, in many cases, been standardized, the same cannot be said for the regulatory processes involved in global sourcing of flavors and fragrances. However, the food and beverage industry—including manufacturers, suppliers and buyers involved in the production, distribution and use of flavors and ingredients—generally agrees that a universal set of standards would make navigating through a labyrinth of regulatory requirements easier and benefit all parties involved. A global standard would make it easy to document the history of a product. It would also be easier to gather information about the processes involved in the production or extraction process, lay out the overall process flow, define the types of catalysts used in a specific process and stipulate the regulations involved.

A universal set of standards for the production of flavors would also allow the development of a set of international audit standards which, after adoption, could then be consistently enforced. Given the increased consumer demand for natural ingredients, such a coherent, global approach would also be important in eliminating the economic incentive to fraudulently label synthetic flavors as natural. Furthermore, it would eliminate regulatory discrepancies.

Given the complexity of the regulatory landscape for natural flavor ingredients, there are still a great number of unknowns and gray areas. Without a consistent, universal set of global standards for natural ingredients, the food and beverage industry, as well as manufacturers, suppliers and buyers, rely on the honesty and trust placed in each other to ensure that product claims are indeed valid and accurate.

Example: One Approach on Naturals

Clearly labeling natural products as US or European naturals, and including a certificate showing the specific regulations met for that specific product, are approaches worth considering. Furthermore, each natural product should be tested by an independent isotopic analytical facility, such as the Center for Applied Isotope Studies (CAIS) at the University of Georgia. In the 1990s, CAIS was one of the centers pioneering the development of the isotopic analytical methods that are now routinely used to differentiate natural and synthetic flavors, ingredients, and manufacturing methods in order to detect adulteration in food and beverage products. Finally, while waiting for the emergence of a universal regulatory process, a rigorous quality assurance process managed by dedicated in-house experts will help to mitigate risk and complexity in the supply chain.

In the end, a universal, global, regulatory process will bring transparency to the marketplace and increase consumer confidence.

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