How Much is Too Much? Regulatory Limits Versus Public Health Limits

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ABSTRACT

Is food safe even when it meets federally-mandated standards? Such "regulatory limits" certainly provide agreed-upon and transparent metrics by which a scientific (and political) consensus can be reached. However, such limits may not be understood or even cared about by the consumer. So often, the consumer simply wants "none" of the chemicals or ingredients that the consumer believes might cause harm. Reconciling these "public health limits" with regulatory limits is inherent to moving food safety and food science forward. This article provides examples of the stressors between these two types of limits and suggestions about how to handle them.

INTRODUCTION

Our food in the United States is safe. As a consumer, how does one assess "how safe" when there are so many factors in play? These factors include where the ingredients come from; how they are handled, processed, and transported; how they are transformed into food; what other ingredients they are mixed with; what chemicals hitch a ride and end up in the food; and how much of the food is consumed.

Hence, we trust others to keep an eye on food safety for us, which is why there are many scientific groups (e.g., the Joint FAO/WHO Expert Committee on Food Additives), regulatory agencies (e.g., the U.S. Food and Drug Administration [FDA] and the U.S. Department of Agriculture [USDA]), state health organizations (e.g., California's Proposition 65), certification bodies (e.g., organic or gluten free), auditing bodies (e.g., the Global Food Safety Initiative), information groups (e.g., the Food Allergy Research and Resource Program, University of Nebraska), and scientific associations (e.g., the International Association for Food Protection). The sum total of their work is to keep our food safe so that we as consumers do not have to worry when we make choices at a supermarket.

GETTING MORE INFORMATION

However, at times we want more information. This desire may be triggered by simple curiosity (because of something you heard or read) or by changes in the nutrition facts label (all food manufacturers are now complying with new rules). Your children may have asked questions about what is in their food, or you may have a relative or friend who had a negative reaction to a food.

Those consumers who dig deeper quickly learn that different limits apply to how much of an ingredient or chemical can be in food. Some limits are defined by regulatory bodies (regulatory limits), and some are determined by what the court of public opinion deems acceptable (public health limits).

An example of a regulatory limit is the speed limit posted on a highway. However, a public health limit can be lower or higher than the regulatory limit, depending upon one's beliefs and value systems or by previous experience (e.g., injuries at an intersection, implying that the posted or agreed-to speed limit should actually be lowered). Some people believe that vehicles should be driven more slowly than the posted speed and certainly no higher. Yet many other people believe that the "regulatory limit" simply provides some guidance and that going faster than this limit is fine. This analogy is appropriate for limits applied to our food ingredients and chemicals.

The USDA *(5)* has provided a thorough summary on its website for "labeling ingredients guidance and inspection methods to protect consumers from misbranding." The FDA *(10)* has provided an inventory of substances allowed in food; this guidance used to be called "Everything Added to Foods in the United States" but is now called "Substances Added to Food."

INGREDIENTS

For ingredients, the issue is usually straightforward because so many foods have federally mandated standards of identity that must be met for the products to be sold. For example, legal definitions exist for vanilla extract versus vanillin. Lists of acceptable additives for foods, such as preservatives, are also publicly available and have the force of law behind them. Manufacturers must use ingredients that are allowed; not doing so is illegal. The ingredients are thoroughly checked by the USDA during their inspections of a company's food and its labeling.

Laws also dictate that the ingredients of a food must be listed on that food's label. All ingredients must be specified (in order of decreasing amounts); thus, an ingredient cannot be added to the food unless it is listed on the label. The exceptions to this requirement are small amounts (<2%) of minor ingredients such as flavors and spices. For example, "natural flavors" can be listed, but the exact ingredients do

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not need to be specified. This is one way that manufacturers protect their secret formulas (such as cola drinks).

However, things are sometimes not as clear as you might hope. In the 1970s, enough negative toxicological data on saccharin use in rodents was obtained that the FDA proposed a ban on the substance *(2)*. Congress overruled this ban and instead required a warning label on products containing saccharin. Over the ensuing years, further analysis of more data convinced the government that saccharin is "not reasonably anticipated to be a human carcinogen" *(4)*. Hence, its use was allowed in the United States beginning in 2000. Was the chemical any less safe in 1970 compared with 1990 or now?

Saccharin also was delisted in Canada in the 1970s *(3)*. Ongoing work by Health Canada revealed that the chemical was acceptable for certain uses and in specific concentrations and thus allowed its use beginning in 2014 *(1)*. Was saccharin less safe in Canada from 2000 to 2014 than it was in the United States during that time period?

HINT: The ingredient and nutrition labels on foods are your best friends. Read them to understand what you and your family will be eating.

CHEMICALS

Chemicals also have limits, and these limits in food are generally more difficult to determine because many thousands of chemicals may enter the food chain. The preservative sodium benzoate has been used since the early 1900s to extend the shelf life of food. Over time, the FDA *(11)* studied scientific research and consumer information on the chemical and declared it generally recognized as safe as long as the concentration in the food was ≤0.1% by weight.

Other chemical examples are pesticides and insecticides such as chlorpyrifos which was a replacement for DDT. These chemicals obviously are not added to food as ingredients but may get carried along in or on an ingredient. Pesticides and insecticides are used worldwide in agribusiness for their putative benefits in facilitating efficient growth of much-needed crops. As with other chemicals that might end up in food, limits have placed on how much, if any, of these chemicals are allowed in food. Agencies such as the U.S. Environmental Protection Agency (EPA) are highly involved with this process, yet many years can go by with either no action or with changes in limits. For chlorpyrifos, most consumer uses of the chemical were banned in 2001, but the product was still allowed on commercial farms. Because of technical and political delays, this chemical was not banned completely until 2022 *(8)*.

The herbicide glyphosate was the subject of an "interim decision" by the EPA *(7)* in January 2020: "EPA has concluded its regulatory review of glyphosate—the most widely used herbicide in the United States. After a thorough review of the best available science … EPA has concluded that there are no risks of concern to human health when glyphosate is used according to the label." A question remains. If glyphosate is that safe, why have manufacturers poured billions of dollars into the research of alternatives?

Some chemicals are imbedded in plastics (e.g., used as processing aids). One of the most well-known of these is bisphenol A (BPA), which has been commonly used to fortify the epoxy resins lining the inside of cans (essentially serving as a barrier to protect the food inside). This chemical has been studied for decades, and various limits have been proposed based on this regulatory and scientific scrutiny. Most manufacturers have moved away from BPA-containing plastics, regardless of where the "limits" have landed. The FDA *(9)* provided an update in November 2014: "FDA's current perspective … is that BPA is safe at the current levels occurring in foods … and the currently approved uses in food containers and packaging." Another question remains. If BPA is 100% safe, why do so many manufacturers (e.g., of baby bottles) advertise BPA-free products?

HINT: Chemicals can do wonderful things to improve the world's food supply. Make your own judgement on whether less is more before you eat.

THE CONFUSION ABOUT REGULATORY LIMITS

The above examples illustrate that the scientific and regulatory bodies consider it their job to use science, medicine, statistics, and objective debate to arrive at well-defined limits for a particular ingredient or chemical. Typically, there is no gray area—the substance is either below such a limit (and therefore deemed safe) or above that limit (and therefore deemed illegal, unsafe, and/or unethical). Yet three major factors continue to influence and change what seem to be hard and fast upper limits: science, consumers, and politics.

Science, technology, and medicine continually progress and shape our knowledge about health and the ingredients and chemicals that affect health and well-being. Monitoring includes measurement of substances in a food or in a human body. Generally speaking, as analytical methods improve over time, lower concentrations of a substance can be detected. Hence, what was nondetectable a decade ago (due to technical limitations) is now detectable at 10 times lower concentrations (because of new techniques).

HINT: Be wary when there is a claim of "nondetectable" or "none found." This does not mean zero. It just means that the techniques provide visibility only down to a certain concentration. Hence, analysis alone does not prove "zero."

Consumers often band together (call them "activists" if you will) to bring attention to something they as a group believe is not getting enough attention. In the case of glyphosate and BPA, without consumer interest, attention, and energy, the amount of information on these compounds that has been obtained over the past decade would likely be far lower.

Politics also play a role in shaping limits, which is natural and expected because the U.S. regulatory bodies are created

through federal laws. For example, how much of the work associated with development of the COVID-19 vaccine was driven by medical need, by politics, and by the need for corporate profits? Many other political examples can be found in the EPA for regulation of air pollution. For limits on materials such as CO_2, how much of the research has been driven by the science supporting climate change, by new equipment that can scrub gases, and by politics?

Amid the haze of changing science, consumers very vocally raising issues, and politicians trying to drive regulatory limits to meet the parochial needs of the people they represent, consumers can take comfort in the fact that limits do get imposed. At a minimum, they provide a target from which further discussion, argument, and scientific development can evolve. Do not get mad at such limits; rejoice that they exist.

THE FUZZINESS OF PUBLIC HEALTH LIMITS

In contrast to limits, many people really want "zero" amounts of an ingredient or chemical of concern. These consumers may be thinking that lower concentrations are always better, and zero concentrations are best. This target can be a fair because more is at stake than just the final measurement of that ingredient or chemical. A common phrase is "you can't test quality in," which means that actions need to be taken from the beginning to ensure that "zero" is achievable.

For food ingredients, actions include consideration of where something is grown, what kinds of farming practices are used, what kinds of controls are in place for the chemicals used on the farm, and what clean-up protocols are used to remove unwanted materials from the ingredient. Testing must be conducted along the way, not just at the end.

A public health limit is therefore different from acceptance of the validity of a regulatory limit set for a specific substance (e.g., a pesticide). In making a risk assessment, the EPA practice is to evaluate aggregate sources *(6)*, as in this "teacup" analogy. Consider the different sources of an undesirable substance (e.g., food, water, your lawn, the air, a hard surface that you touch), and put each amount into a teacup. The regulatory limits would indicate that the amount from each separate source is "safe," but if you put all of those insults into one teacup, would you drink from that teacup?

HINT: Always remember that the human body is a remarkable machine, able to take in various chemicals from the environment, metabolize them appropriately, and then excrete them, all with no harm done.

LIMIT YOURSELF

By now you just might be more confused or more worried. Overall, the people who are setting limits can be trusted to make, on par, the right decisions. However, regulatory limits are just that—founded on regulations based on the current science that has been peer reviewed but still subject to debate. The resulting limits might be compromises but do act as standards against which a food ingredient can be measured. This process is conducted professionally and diligently because regulatory limits have the force of law. This approach levels the playing field, catalyzes honesty and transparency, and truly puts maximum limits on substances, ingredients, and chemicals.

However, imperfections in the process exist, especially when the results are in conflict with personal value systems. Thus, consumers may need to become more involved in the process and better educated. Consumers can make their choices speak at the supermarket! Just make sure you do not exceed the speed limit as you drive there.

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