# *Module 11, Lesson 2 Handout:*
# GRAS

GRAS. It stands for "generally recognized as safe," and it's the bit of legislation that controls the additives in our food supply. GRAS is overseen by the FDA, and while it sounds reassuring, the history of GRAS and what it really means can get pretty controversial and downright confusing. We'll summarize it here.

**History and Definition**

The concept of GRAS began in 1958 under the Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act (FD&C Act). The amendment laid out the definition of the term 'food additive' and established a review process for companies to prove the safety of these additives. Sounds great, but there was a loophole to help save time for common ingredients like baking soda and vinegar. Any ingredients like these that were already widely used and known to be safe were considered GRAS and didn't have to go through the same safety review process as other food additives.

**How Does Something Become GRAS?**

There are two ways for something to be deemed GRAS. First, as we explained above, ingredients used before the 1958 legislation that had a substantial history of being used in common foods that were eaten by a lot of people were basically GRAS by default.

Second, something can be considered GRAS if there is widely accepted scientific data and consensus among qualified experts that the substance is safe under the conditions of its intended use. However, the government doesn't actually need to be involved in this process. In 1997, the FDA introduced a rule that lets companies decide for themselves what ingredients qualify as GRAS, called GRAS notification. In short, a company can put together its own panel of experts who can decide if the ingredient is safe. They can then report those safety designations to the FDA on a *voluntary* basis - yes, voluntary, meaning they don't actually have to share the results. This is where things become pretty sketchy. .

The law was slightly updated in 2016, but things still aren't great. The current regulations state "any person may notify FDA of a conclusion that a substance is GRAS under the conditions of its intended use" and "of a view that a substance is not subject to the premarket approval requirements… based on that person's conclusion that the substance is GRAS under the conditions of its intended use."

‚So basically, food companies can submit safety reports to the FDA, and while the FDA has the opportunity to review the reports, we still wind up with ingredients on the GRAS list which may not have undergone adequate peer review.

So if companies don't need to report safety results to the FDA, what do they actually need to report? Here are the basic steps for getting an ingredient on the GRAS list:

1. Inform the FDA you are submitting a GRAS notice
2. Provide the name and address of your company
3. Provide the name of the substance/ingredient
4. Describe the intended use of the notified ingredient (what foods it will be added to, the amount that will be used in the food, etc.)
5. Let the FDA know your basis for deciding the ingredient is GRAS (for example, were there studies?)
6. State that you believe the ingredient is not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act based on your decision that the ingredient is GRAS
7. State that, *if the FDA asks* to see your study results you will agree to make it available
8. Certify that to the best of your knowledge the GRAS notice is accurate.
9. Have someone sign the GRAS notice

Yep, that's it.

**Bottom Line**

GRAS began to help save time and cut down on the review process for ingredients that were obviously safe, but where it stands today, it's become a lot easier for companies to bypass government oversight and for less-than-safe ingredients to end up in our food. We know this isn't a perfect process because we've seen ingredients lose GRAS status; this is what happened with partially hydrogenated oils and why they are no longer allowed in the food supply. In the past few years we've also seen the FDA reverse GRAS status on several types of food flavorings due to evidence of being carcinogens.

So what do you tell your clients? First of all, we want to cut down on packaged processed foods anyway, and doing this can help avoid eating sketchy ingredients. Educate clients on how to read an ingredients label, and remind them that just because something has GRAS status and is in our food supply doesn't mean it's 100% safe. We see many examples where something is considered GRAS in the US but is banned in Europe, such as potassium bromate and azodicarbonamide found in breads

in the United States. If a client is uncertain about an ingredient in a food, most likely it shouldn't be part of their regular diets but a good resource to check is also the EWG Food Scores database at www.ewg.org/foodscores. You can search by ingredient to find out exactly what something is, and there is other good information about ingredients and additives on this site as well.